THE MID STAFFORDSHIRE
NHS FOUNDATION TRUST
PUBLIC INQUIRY

Chaired by Robert Francis QC

Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry

Volume 2: Analysis of evidence and lessons learned (part 2)

HC 898-II

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February 2013

Volume 2: Analysis of evidence and lessons learned (part 2)

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Chapter 8
Performance management and the strategic health authorities

Key themes

- There was a significant gap between the legislative and policy theory of the role of strategic health authorities (SHAs) and their capacity to carry this role out – eg performance management versus taking a strategic overview, the resourcing of the new SHAs versus their monitoring role, and the SHA's remit in relation to quality.
- The implementation of the regular reorganisation of the NHS led to misunderstandings about functions, poor handovers of information, and a gap through which a provider's poor performance could pass unnoticed.
- The SHA made no link between its roles in relation to finance and workforce and how these may impact on patients and quality of care – it prioritised targets not patients and focused on finance not quality.
- The SHA saw its role as defending the Trust against the Healthcare Commission (HCC), particularly in relation to Hospital Standardised Mortality Ratios (HSMRs), rather than holding it to account – it tended to seek justifications not remedies for concerns and had an over-ready acceptance of action plans.
- There was an over-reliance upon the assurances given by the Trust Board and a lack of scrutiny and challenge.
- The SHA regarded failures to meet accident and emergency (A&E) targets as issues to be performance managed rather than seeking the underlying causes for such failures.
- The SHA's approach to the HSMR concerns was to focus on coding and on rebuttal, rather than looking at the possibility of poor care.
- The SHA knew it was lacking information about quality, which is difficult to measure, but failed to translate this into extra vigilance in checking for warning signs.

Legislative and policy background

8.1 With effect from 1 October 2002 a number of functions of the Secretary of State were delegated to the newly created strategic health authorities (SHAs) subject to such limitations as he might direct and further subject to any directions he might give.[1] These included:

- Jointly with primary care trusts (PCTs), the provision of services under Section 2 of the National Health Service Act 1977;
- Jointly with PCTs for the purpose of performance management only, the provision of hospital and other accommodation, facilities for the prevention of illness, the care of persons suffering from illness and aftercare, and other services for diagnosis;
- The duty to promote a comprehensive health service;
- The giving of directions to NHS trusts about the exercise of any of their functions (but not foundation trusts (FTs));
- The SHA was required to exercise these functions for the benefit of the area and to secure effective provision of services by PCTs and NHS trusts for which they were the appropriate SHA.[2]

8.2 In *Shifting the Balance of Power: The Next Steps*, published in January 2002, the Department of Health (DH), set out the functions of SHAs as follows:

> *2.2.3 The three key functions of a Strategic Health Authority are:*
>
> - *creating a coherent strategic framework;*
> - *agreeing annual performance agreements and performance management;*
> - *building capacity and supporting performance improvement.*[3]

8.3 The document also set out the "clear principles about the style of SHA working", which should be:

> - *focused on delivery – agreeing and reviewing local delivery plans, securing improvement for both the short and longer term; where necessary intervening to secure improved performance. Consistent performance management principles will apply across all SHAs.*
> - *committed to service quality and patient safety – creating the environment where they are at the centre of decision-making.*

1 IRC/4 WS0000016747; *The National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administration Arrangements) (England) Regulations 2002* [SI2002/2375], Regulations 3 and 6, Schedules 1 and 2, www.legislation.gov.uk/uksi/2002/2375/contents/made

2 Cumming WS0000016661, para 17; IRC/4 WS0000016747; *The National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administration Arrangements) (England) Regulations 2002* [SI2002/2375], Regulations 3, 6 and 7, Schedule 2, www.legislation.gov.uk/uksi/2002/2375/contents/made

3 DH00060000001, *Shifting the Balance of Power: The next steps* (January 2002), Department of Health, p 10

- *empowering – seeking to devolve power to the frontline and to patients and the public and supporting them in tackling the improvement of the NHS. StHAs should focus on their core roles and not seek to retain those functions which could be operated on a collaborative basis across PCTs and NHS Trusts.*[4]

8.4 The document listed among the "specific activity" expected of the new SHAs:

> *... ensuring the delivery of safe, quality services through effective clinical governance arrangements in PCTs and in NHS Trusts.*[5]

8.5 Professor Ian Cumming, current Chief Executive of NHS West Midlands (formerly West Midlands SHA (WMSHA)), told the Inquiry that this all meant:

> *In practical terms, SHAs act as the regional headquarters of the NHS, providing strategic direction and leadership to the local health community to improve the healthcare offered and provided in that area, commissioning education and training, overseeing public health matters and arranging appropriate emergency planning.*[6]

8.6 He emphasised that SHAs were accountable to the DH, but were not regional offices of the DH. SHAs are staffed by NHS employees, not civil servants, and many come from a clinical background. Each SHA has its own board, including non-executive directors, to ensure that, in addition to being held to account for the delivery of national priorities, they also take into account local and regional needs.[7]

8.7 The chief executives of SHAs sat on the NHS Management Board and the NHS Operations Board, which were staffed with about 50% NHS staff and 50% senior DH staff.[8]

8.8 Sir David Nicholson, NHS Chief Executive, said:

> *I was also very clear that the role of an SHA was, as the name suggests, to be strategic. As well as their day-to-day performance management responsibilities, a key role of the SHA is to provide a strategic direction for the wider health care economy, underpinned by a set of business processes that have a rigour, so that there is a clear connection between the overall strategy and what they deliver.*[9]

4 DH00060000001, *Shifting the Balance of Power: The next steps* (January 2002), Department of Health, p 11
5 DH00060000001, *Shifting the Balance of Power: The next steps* (January 2002), Department of Health, p 12
6 Cumming WS0000016662, para 20
7 Cumming WS0000016662, para 20
8 Cumming WS0000016662, para 21
9 Nicholson WS0000067648, para 64

Performance management

8.9 The 2002 policy document *Shifting the Balance of Power* laid the responsibility for performance management on the SHAs:

> *With performance management delegated mainly to StHAs they will in effect be responsible for managing NHS locally on behalf of the Department.*[10]

8.10 It described how this function was to be performed:

> *Increasingly performance assessment will rely on external and publicly available information and assessment provided, for example, through the performance rating (star) system or CHI* [Commission for Health Improvement] *inspections.*
>
> *In future it will be StHAs which will take on the main performance management function. They will negotiate Trust and PCT annual performance agreements; monitor in-year performance; address under performance; oversee the development of recovery plans and monitor their implementation, providing support to the local NHS to assist under performing organisations; and, assess the adequacy of local operational plans ...*
>
> *The way performance management is undertaken will also need to change to reflect the following principles:*
>
> - *organisations will be assessed on the basis of performance against a small group of priorities and progress towards the longer term vision of the NHS.*
> - *performance management of StHAs, PCTs and NHS Trusts will adopt the principles of earned autonomy to allow high performing organisations the greatest level of operational freedom. Such organisations will be subject to lighter touch financial, operational and monitoring requirements.*
> - *performance management will give more attention to health outcomes and patient impact. In particular PCTs will be performance managed on the outcomes of the care that they provide (including preventive health improvement work and the commissioning of acute services). Process indicators that currently stand as proxies for outcomes will increasingly be phased out, giving PCTs much more operational freedom in the way their services are configured and run.*
> - *the new performance management system will place maximum responsibility on organisations to manage their own performance. They should report on information which they need for themselves.*[11]

8.11 Thus performance management was to be approached by way of monitoring a limited set of indicators, placing increased reliance on externally provided information and allowing

10 DH00060000011, *Shifting the Balance of Power: The next steps* (January 2002), Department of Health, p 10
11 DH00060000023, *Shifting the Balance of Power: The next steps* (January 2002), Department of Health, pp 22–3

organisations that performed well greater autonomy. The role of SHAs in performance management was to be somewhat circumscribed by the emphasis placed on the responsibility of organisations to performance manage themselves.

The approach to quality issues

8.12 "Quality and Safety: Maintaining and Developing the NHS Quality Framework", an appendix to *Shifting the Balance of Power*, included the following:

> *a. Duty of Quality*
>
> *Every local NHS organisation has a statutory duty to assure, monitor and improve the quality of its services. This has been implemented through the clinical governance programme. Primary Care Trusts are required to have robust clinical governance arrangements in place as well as to ensure that in commissioning services from NHS and other providers that quality and safety are core elements of their commissioning decisions.*[12]

8.13 The statute, which was in force in England from April 2004 to March 2010, expressed the statutory duty of quality in the following way:

> *45 Quality in health care*
>
> *(1) It is the duty of each NHS body to put and keep in place arrangements for the purpose of monitoring and improving the quality of health care provided by and for that body.*[13]

8.14 This duty applied as much to SHAs as it did to any other NHS organisation.

Capacity of strategic health authorities

8.15 SHAs were very much more limited organisations than the regional health authorities (RHAs) which preceded them prior to the 2002/03 reorganisation. RHAs were very large, each having some 2,000 staff. The policy objective of the change was to make substantial savings in administrative costs and move the money saved to "front-line" services, devolving the principal exercise of any functions which had been performed by RHAs to the PCTs. *Shifting the Balance of Power* explained the process in this way:

> *Shifting the Balance of Power will mean reducing the whole staffing and management costs of the intermediate tier – Health Authorities and Regional Offices – and devolving maximum resource to frontline organisations and in particular to Primary Care Trusts ...*

12 DH00060000045, *Shifting the Balance of Power: The next steps* (January 2002), Department of Health, p 44
13 Health and Social Care (Community Health and Standards) Act 2003, Section 45, www.legislation.gov.uk/ukpga/2003/43/contents

Strategic Health Authorities will have a cap on their staffing numbers of 75 staff and £4m of running costs.[14]

8.16 Professor Cumming emphasised the resulting limitations on the role of SHAs:

> [T]*he name "strategic health authority" was deliberately chosen to differentiate from the regional health authorities ...* [which] *used to employ somewhere in the region of 2,000 members of staff and ... were expected to manage the health service and the delivery of healthcare in their area ... Shifting the Balance of Power ... makes it clear that the size of a strategic health authority should be 75 people ... covering 5,000 square miles, looking after GBP 10 billion of money a year and with a responsibility for more than 50 NHS organisations ... These are very small organisations, with an emphasis on – on the S in SHA, strategic.*[15]

8.17 He pointed out that the WMSHA, after its creation in 2006, had one and a half members of staff for each NHS organisation for which it was responsible.[16] Sir David Nicholson was clear that it had not been the intention for SHAs to performance manage providers and they were not given the capacity to do so.[17]

Organisation and reorganisation

8.18 The period under review by this Inquiry was one of considerable organisational change at SHA level. This resulted in changes in the personnel and structures responsible for the oversight of the Trust. There is little doubt that the demands of reorganisation and the limited staff and other resources available seriously restricted the ability of the SHA to perform an effective role in performance management.

From 2002 to 2006

8.19 From the inception of SHAs in 2002 until 2006, there were 28 SHAs responsible for 303 PCTs.[18] At the beginning of this period, there were 579 trusts in England providing services, as rated by the Commission for Health Improvement (CHI).[19] Shropshire and Staffordshire SHA (SaSSHA) had responsibility for 18 organisations, one of which was the Trust. Although it was only allowed to have around 47 staff, its Chairman at the time, Mike Brereton, told the Inquiry that it had not had difficulty in fulfilling its duties on that account.[20]

14 DH00060000014, *Shifting the Balance of Power: the next steps* (January 2002), Department of Health, pp 13–14
15 Cumming T67.14–15
16 Cumming WS0000016665, para 34
17 Nicholson WS0000067650–51, para 71
18 Nicholson WS0000067636, para 19
19 The Commission for Health Improvement star ratings for 2002/03 covered acute, ambulance, mental health, specialist and primary care trusts, totalling 579 trusts altogether – see *NHS Performance Ratings: Acute trusts, specialist trusts, ambulance trusts – 2002/2003* (July 2003) Commission for Health Improvement, p 10, www.chi.nhs.uk/Ratings/more_information.asp
20 Brereton WS0000037190, para 8

2006 reorganisation: strategic health authority merger

Underlying policy

8.20 In *Creating a Patient-led NHS*, published in March 2005, the Government gave notice of a reorganisation of PCTs and SHAs in England. The announced purpose was to shift the focus of performance management from SHAs to PCTs:

> *SHAs currently have responsibility for strategic direction, the development of the NHS locally and performance management. In future the direct performance management role will become less resource intensive, as performance management is focused through PCTs, with a more autonomous provider base.*[21]

8.21 The detailed expectations and timetable for this reorganisation were set out in the document *Commissioning a Patient-led NHS*, which was published and circulated to the NHS by Sir Nigel Crisp (NHS Chief Executive and the DH Permanent Secretary at the time) on 28 July 2005.[22]

8.22 This transfer of performance management away from SHAs was intended to coincide with the grant of greater independence to provider organisations. The same document also stated again the intention that all NHS trusts would have the opportunity to apply for FT status by 2008, a process in which the new SHAs were expected actively to assist.[23] FTs were not to be line managed within the NHS hierarchy leading down from the NHS Chief Executive, but were to be overseen by Monitor, the independent regulator of FTs, with services being commissioned for the NHS through PCTs.

8.23 Had the transfer of NHS trusts to FT status gone according to the 2005 plan, a significant workload might have been lifted from SHAs. However, progress in this regard fell behind the reductions in staff and resources imposed upon the SHAs in order to make cost savings. Indeed, Sir David Nicholson told the Inquiry in his oral evidence in September 2011 that only some 60% to 70% of patients were being treated in FT hospitals.[24] At the same time, the roles of the regional and SHA directors of public health were merged and rationalised, to be brought under the SHA umbrella, and regional postgraduate deaneries and workforce confederations were merged into the SHAs.[25] The number of SHAs was drastically reduced from 28 to 10.

Change in the West Midlands

8.24 In July and August 2006, SaSSHA, the Birmingham and the Black Country SHA (BBCSHA), and West Midlands South SHA were merged into one authority, the WMSHA. At about the same

21 JL/1 WS0000022394, para 5.14
22 DH00000001174
23 JL WS0000022394, para 5.8
24 Nicolson T127.80–81
25 Cumming WS0000016664, para 27; Shukla WS0000018530, para 5

time, the 30 West Midlands PCTs were reduced in number to 17. WMSHA became responsible for 57 NHS organisations with a combined annual budget of £6.5 billion and covering a population of 5.4 million.[26]

8.25 Prior to the merger, there were considerable changes in SHA senior personnel. Bernard Crump relinquished his post as Chair of SaSSHA, and the Chief Executive of West Midlands South SHA also left. David Nicholson, who had been Chief Executive of BBCSHA, also became Interim Chief Executive of West Midlands South SHA and of SaSSHA in July and August 2005 respectively. He had responsibility for merging the three SHAs and appointed managing directors to each. David Nicholson left this role in June 2006 and Cynthia Bower became Interim Chief Executive of the new WMSHA in July 2006, taking this post up substantively in March the following year.[27]

8.26 The new SHAs were required to work within a fixed budget and to reduce staff. In the case of the WMSHA, it had to reduce the staff of the predecessor SHAs by 60% to an establishment of 75, excluding the deanery.[28] The WMSHA inherited a combined deficit of £37 million from its predecessors, and an obligation to break even. A "sizeable" redundancy programme was required, which was still running in 2007.[29] Other tasks connected with the reorganisation included the merger of the postgraduate deanery and workforce confederation, the challenge of introducing Modernising Medical Careers, and management of the combined deficit.

Handover arrangements

8.27 There was no system in place to arrange for the merger of the three SHAs or to guarantee continuity. As Ms Bower put it:

> *Upon the transition from three SHAs into one, no due diligence process was carried out and I am not aware of any formal handover meetings between the former SHAs and the new WMSHA taking place.*[30]

8.28 There was a transition team, which principally focused on setting up the system within the new SHA, but not on ensuring that knowledge from the predecessor organisations would be passed into the new one. Ms Bower made it clear that she relied on an assumption that if there were concerns known within the predecessor organisations about a trust, these would be passed on, and this had indeed occurred in various instances. No concerns had been brought to her attention about the Trust.[31]

26 Cumming WS0000016663–4, paras 24–5
27 Nicholson WS0000067631, para 4; Bower WS0000020974–5, para 7. Cynthia Bower was appointed to this post at BBCSHA, Antony Sumara at SaSSHA, and Catherine Griffiths at West Midlands South SHA.
28 Cumming WS0000016665, para 34
29 Bower WS0000020978–9, paras 18–19
30 Bower WS(1) WS0000020977, para 15
31 Bower WS0000020978, para 17

8.29 Reflecting on the matter, Ms Bower accepted that transfer of knowledge was important and should have been approached systematically:

> *In any reorganisation, organisations need to share what they know and have learnt from their experiences with their successor body. For a supervisory body, this transfer of knowledge should include a comprehensive handover of what information is held on each of the organisations under their oversight. To the best of my knowledge no such "due diligence" process existed in the NHS at the time of the 2006 re-organisation, but this is something that should be considered in future.*[32]

8.30 Sir David Nicholson, who was in a position to see the effects of the reorganisation at the time, was asked how it had affected performance:

> *Q. To what extent was it recognised that the organisational change in the PCTs and the SHAs was likely to lead to a loss of quality of commissioning? Do you accept that, first of all, that that was the practical reality locally?*
>
> *A. Not everywhere were there significant change* [sic] *in PCT configuration. There were parts of the country where it stayed the same. And so it wasn't everywhere that you suddenly got new PCTs being made and all the rest of it. But, clearly, all the evidence around organisational change shows that there is a time of risk for the organisation, and there's a time very often, if you look at evidence in other areas, where performance can dip.*
>
> *Q. Was that recognised by Government, that that was a danger and there was, therefore, a danger in the loss of quality in the commissioning process?*
>
> *A. ... I think it – I think the danger was recognised, and what we did was try to mitigate that. I don't think it was a big part of the decision to decide whether the Government were going to have Commissioning a Patient-led NHS or not, but certainly in the actions that we took afterwards, we attempted to mitigate the implications of that, as far as we possibly could.*[33]

8.31 The demanding task that faced David Nicholson's managerial team was made no easier by the inevitable tensions change caused to all concerned. As he said:

> *The majority of the people tasked with delivering this complex agenda had no certainty about their own future, and no guarantee where, if at all, they or their teams would be working.*[34]

32 Bower WS0000021020, para 153
33 Nicholson T127.28–29
34 Nicholson WS0000067652, para 76

8.32 Sir David described to the Inquiry the steps he took to mitigate the risk of organisational memory loss, but accepted that in hindsight:

> *... we were not alert to potential problems arising similar to those that were identified at* [the Trust]. *Our activities did not focus sufficiently on quality of care issues that might occur during transition.*[35]

8.33 He contrasted this with the different approach being taken, as a result of the lessons learned, with regard to the current round of reforms. For example, Professor Cumming had been commissioned to produce a paper on best practice in the management of transitions, and the National Quality Board (NQB) has worked on early warning systems during the transition period.[36]

Performance management handover

8.34 No handover letter was created by SaSSHA staff for use by the WMSHA on performance management issues, even to the relatively limited extent that occurred for financial matters. Philip Taylor, Director of Performance and Finance and Deputy Chief Executive at SaSSHA, explained this by saying that the performance staff had already been transferred to the WMSHA and would have taken their records, and presumably knowledge, with them.[37] It is clear, in any event, that SaSSHA did not have any non-financial performance management concerns about the Trust of which it was aware to hand over to the WMSHA.

Medical Director/public health handover

8.35 Dr Rashmi Shukla arrived as Director of Public Health and Medical Director of the SHA in July 2006. She had no previous knowledge of health services in the West Midlands before July 2004 and before July 2006 she had no NHS responsibilities included in her role. Her predecessor as Director of Public Health had already departed and the post of Medical Director was new. She received no formal handover briefing discussions with former SaSSHA staff. She received two brief documents, one of which appears to have been an incomplete draft, from Dr Paulette Myers, the former Head of Clinical Governance/Consultant in Public Health at SaSSHA, in July and August 2006.[38]

35 Nicholson WS0000067655, para 86
36 Nicholson WS0000067655–6, para 86
37 Philip Taylor WS0005000443, paras 75–8
38 Shukla WS0000018544–5, paras 52–3; RS/14 WS0000018759; RS/15 WS0000018762

8.36 They were less than informative. For example, in relation to serious untoward incidents (SUIs), the more complete of the two documents informed Dr Shukla that:

> *The SHA has received reports on a number of SUIs across a spectrum of services (as would be expected). Officers follow up local organisations to ensure that appropriate internal investigations have occurred. We are struggling to keep up with the chasing of reports and outcomes as all the SASHA clinical governance team (bar me) have now left. I have spoken to ... to see if we can get more admin support to analyse SUI performance.*[39]

8.37 There was virtually no reference to individual organisations apart from a brief mention of deaths in custody (one of which happened to have been at the Trust).

8.38 Dr Myers was certain there were other documents available and also that information would have been passed on at meetings, and Dr Shukla agreed that there would have been other conversations.[40]

8.39 Dr Shukla accepted that, with the benefit of hindsight, the handover had not been satisfactory:

> *... in terms of handover, we relied on exceptional reporting ... from individuals as the means to know what clinical risk or clinical issues may be ongoing in organisations as the transition happens. What ... I think, with the benefit of hindsight clearly is that there needs to be a collective effort to ensure that each organisation is risk assessed, irrespective of whether there is any concern or not at the time, and that is part of the handover documentation from the outgoing organisation to the incoming organisation ...*[41]

8.40 If, as suggested by Dr Myers, there were other documents available at the time, Dr Shukla appears not to have received them. In the absence of an expectation of a formal handover arrangement with a handover briefing containing the sort of information described by her in her evidence, the transfer of corporate memory was likely to be deficient. If documents have gone missing that would be additional confirmation of this point.

Effect on priorities

8.41 Ms Bower told the Inquiry that, in July 2006, the tasks immediately confronting the WMSHA because of the reorganisation were:

- The reduction in size of the WMSHA;
- The integration of the postgraduate deanery and workforce confederations;
- The management of the overall deficit and financial issues inherited from the former SHAs;
- The creation of new PCTs and a new regional ambulance service.[42]

39 RS/15 WS0000018766
40 Myers T100.93; Shukla T68.75–76
41 Shukla T68.75
42 Bower WS0000020978–9, para 18

8.42 At an early meeting of the WMSHA Board, in July 2006, Ms Bower emphasised the intention to engage patients and the public in the decisions of the authority:

> *The SHA's growing intelligence base about what our local population think of local services and what they hope and expect from the future for* [sic] *the cornerstone of our decisions and judgements. The* [West Midlands] *NHS will be the advocates for patients and citizens, not NHS organisations.*[43]

8.43 One of the methods adopted to try to achieve this was the use of patient surveys, but these were not designed, nor were they sensitive enough, to detect concerns about quality at individual trusts, as the objective was to provide support for strategic planning.[44] Other methods of engaging the public were promoted through the Investing for Health programme (see below), the development of NHS Local (through which patients could voice their views directly) and the creation of a patients' panel.[45]

8.44 While Ms Bower did not consider that the WMSHA's focus of work and concern in relation to quality issues was diminished by the reorganisation, what that meant is illustrated by her reference to the *Investing for Health* document published by the WMSHA in November 2007, the focus of which was very much on strategy.[46] It can also be seen in her initial priorities as Chief Executive:

- *To deliver the targets required of the local NHS by the Department of Health. Most notably the transition team, led by the then Chief Executive, had developed a clear financial strategy to delivery financial balance in 2006/07 and it was my responsibility to achieve this balance;*
- *To deliver the workforce of the future through workforce planning and development …;*
- *To develop PCTs to become the main driver for healthcare improvement, delivery and reform for their local population;*
- *To ensure all NHS trusts would be capable of becoming FTs.*[47]

8.45 She pointed out that the SHA's responsibility for workforce planning did not extend to monitoring the patient/clinician ratio but was a matter of ensuring the supply of staff and training:

> *I am absolutely clear that it was not the responsibility of the WMSHA to ensure that there was a safe level of staff to deliver an acceptable quality of care – this was the responsibility of the organisation itself.*[48]

43 CB/5 WS0000021244; Bower T73.52–53
44 Bower T73.55
45 Bower T73.56–7
46 Bower WS0000020980, para 21; CB/4 WS0000021079
47 Bower WS0000020987, para 42
48 Bower WS0000020988, para 45

8.46 Ms Bower's priorities reflected those handed down to SHAs from the DH. They focused on policy objectives directed largely at finance and restructuring of the NHS system as a whole, but very little on the quality of care delivered by this system. The assumption was clearly that provider organisations were capable of delivering safety and quality without detailed performance management, but what was needed in that regard could and would be provided by the enlarged in size, but reduced in number, PCTs. It is noteworthy that the protection of patients does not figure expressly at all in her priorities, although she would doubtless argue that such a concept underlay all of them.

The strategic health authority approach to quality

Shropshire and Staffordshire Strategic Health Authority

8.47 SaSSHA did appreciate that it had a duty with regard to quality but it appears to have assumed that quality was being protected if other areas of performance were monitored. Mr Brereton was asked about the SaSSHA view on quality:

> *Q ... Did your organisation, did you, appreciate from the outset that you needed to have an emphasis on securing or ensuring safe and good-quality care from NHS trusts on your patch?*
>
> *A. I think it's fair to say that patient safety and the patient experience we always regarded as implicit in the project, and implicit to NHS organisations. It's almost a bottom line starting point. Did we set out specifically to prioritise that over the other tasks we'd been set? I don't think so, because it was a drum beat which underpinned everything we did.*[49]

8.48 As will be seen, there were issues at the Trust of which SaSSHA was aware, but none that distinguished it from other trusts in the area:

> *There were trusts on the SaSSHA patch ... which had problems and challenges of an order of magnitude greater, if I can use – than this Trust did. No, that's not to say that we didn't take this Trust's challenges seriously. But many of the things we've been looking at today in these reports are the sorts of issues that would have arisen in most trusts at this time and were being addressed in most trusts at this time. And I may add that they carried on being flagged because the bar that we were setting for performance ... was being raised year by year, and that was deliberate, and so – and as were the targets, in fact. And that was deliberate also.*[50]

49 Brereton T97.6
50 Brereton T97.75–76

8.49 It is clear from the evidence that the monitoring of quality and safety performance by SaSSHA was limited largely to examining compliance with certain national targets.

8.50 Mr Philip Taylor told the Inquiry:

> *... the targets were set by the Department of Health and we monitored how the organisations were performing against these targets. There were other measures that we were interested in as well but this was our main focus ...*[51]

8.51 He listed the key performance indicators (KPIs) for 2004/05 and 2005/06.[52]

Table 8.1: Key performance indicators monitored by SaSSHA

KPI	2004/05	2005/06
Activity levels	✓	
Waiting lists	✓	
Over 9 month inpatient waits	✓	
Patients waiting between 6 and 9 months	✓	
Over 17 week outpatient waits	✓	
Waiting times in A&E	✓	✓
Primary care access	✓	
Ambulance response times	✓	
Elective access		✓
Finance		✓
Cancer waiting times		✓
Patient choice and booking		✓
Agenda for Change		✓
Towards cleaner hospitals (including healthcare associated infections)		✓

8.52 It is to be noted that, with one exception, each of the indicators prescribed by the DH were completely changed from one year to the next. Few directly related to the outcome of treatment interventions, or to quality and safety of care when delivered.

8.53 At SaSSHA, the Head of Performance Management, Martin Harris, had regular meetings with performance staff at the organisations for which SaSSHA was responsible. He reported to Philip Taylor. Where specific problems came to light, Mr Taylor would join in the discussions. However, the information considered was almost exclusively that generated by the trusts themselves in relation to the targets.[53]

51 Philip Taylor WS0005000438, para 55
52 Philip Taylor WS0005000438–9, paras 56–7
53 Philip Taylor WS0005000439, para 58

8.54 Mr Taylor was clear that the performance team did not inspect clinical facilities and he did not recall the team visiting NHS organisations other than to meet managers. Anything relating to patient safety or clinical governance would not have been a matter for the performance team but would instead have been a matter for the SHA's health strategy team led by Dr Rosemary Geller, which included Dr Paulette Myers.[54]

8.55 Karen Morrey, who worked for SaSSHA in 2005, confirmed this:

> *The only clinical or quality aspect* [of performance management] *was the MRSA figures.*[55]

8.56 Sir David Nicholson told the Inquiry that, when he took over as Interim Chief Executive of SaSSHA in August 2005, he found a very different culture from that to which he had been accustomed at BBCSHA. The latter had been more interventionist, with a proactive role in performance management with regard to quality, finance and service reconfiguration, whereas SaSSHA had seen itself more as a facilitator. While he accepted that the differences of approach had been within the variation allowed by policy, which encouraged SHAs to adopt their own styles, he did feel that the non-interventionist approach had led to SaSSHA failing to tackle the financial issues in the area sooner.[56]

8.57 Dr Paulette Myers suggested that SaSSHA was more proactive than this and cited her work in promoting clinical governance.[57] She was Director of Clinical Governance, and headed a team that was located in SaSSHA's strategy directorate, not its performance directorate.[58] Her role was to support 19 trusts in improving their clinical governance in accordance with CHI guidance. She did not see her role as a managerial one, but rather one of assistance.[59] She was also part of the risk management group, which received reports from her on clinical governance issues, including a summary of SUI data.[60]

8.58 SaSSHA issued a protocol for the handling of SUIs in November 2004. This required trusts to report SUIs within 24 hours. The SHA Chief Executive would be notified immediately and either Dr Myers or her deputy would consider the initial report and generally liaise with the relevant trust. A report was required from the trust of the action necessary as a result of the SUI, and a final report, including a root-cause analysis, had to be given to the SHA within 40 days. On occasion, visits to trusts would be prompted by an SUI, but it would have been impractical to visit each trust in relation to each SUI. While regular routine reports were prepared for various committees, they were provided in summary form (no further detail being required),

54 Philip Taylor WS0005000437–8, para 53
55 Morrey WS0000011197, para 2
56 Nicholson WS0000067657–8, paras 91–3
57 Myers T100.16
58 Myers WS0000037060, paras 7–8
59 Myers WS0000037061, para 12; WS0000037063, paras 19–20
60 Myers WS0000037067–8, paras 36–9

giving broad categories across the region rather than giving detail about individual cases.[61] Dr Myers gave examples of instances where SUIs led to more in-depth investigations and reports:

- An incident involving intrathecal chemotherapy at another trust included in a report presented at a meeting of the SaSSHA clinical governance report risk group;[62]
- A review of comparable services in the region following a CHI report into poor care of elderly mental health patients at Manchester Health and Social Care Trust in September 2003;[63]
- A review of Staffordshire Ambulance Trust in 2004 following two SUIs and a lack of confidence expressed in the response.[64]

8.59 As a system for monitoring SUIs and the identification and implementation of necessary remedial action, in general this may not have been very effective. Trudi-Anne Williams of the Trust told the Inquiry that she would not have expected SaSSHA to monitor the Trust on whether action plans had been implemented.[65]

8.60 SaSSHA's approach to monitoring quality issues was, in part, probably influenced by the expectation that PCTs would increasingly take an active role in this area. Dr Myers told the Inquiry that by 2005, SaSSHA expected PCTs to include in their service-level agreements with providers requirements to report their SUIs to PCTs, to participate in specified audits and to report the results:

> *... there would be, we would hope, within the contracts very clear specifications that would require the provider trusts to take part in key audits, and so I think most contracts would have clauses that said take part in national audits, for example, MINAP* [Myocardial Ischaemia National Audit Project] *or the stroke central audit, or the Royal College of Physicians audit on falls. And then the primary care trust, as they developed their systems, could well specify specific audits, for example, of asthma care, and that was within their gift, and they would then be expected to receive those audits and comment on them.*[66]

8.61 Unfortunately, as the Inquiry was told by William Price and Susan Fisher of South West Staffordshire Primary Care Trust (SWSPCT), the Trust never undertook this requirement in any meaningful way.[67] Further, Dr Myers told the Inquiry that the achievements of PCTs in commissioning for quality effectively were variable at the time:

61 SHA00000000275, *Serious Untoward Incident Protocol* (November 2004), SaSSHA, para 6.1; Myers WS0000037069, paras 43–6
62 PM/1 WS0000037087
63 Myers T100.22–23; PM/2 WS0000037097
64 Myers T100.24
65 Trudi-Anne Williams T133.10–11
66 Myers T100.11–12
67 Price WS0000016115, para 50; WS0000016116, para 55; Fisher WS0000042308, para 44

I think there was variable performance across the PCTs. Certainly the PCTs generally in our patch required more support from us than the acute and ambulance and mental health trusts. There was some excellent examples and there were others who still struggled to cover all the bases. But all were improving. But I can't say all were in the top quartile, for example, in terms of performance.[68]

8.62 Dr Myers saw the process as a "progressive delegation" from the SHAs to the PCTs, which was intended to be accentuated following the reorganisation.[69]

8.63 Another source of information for SaSSHA was the peer review reports undertaken by the West Midlands peer review team. The peer review team was organisationally separate from SaSSHA, although it worked from the same address and used the SHA logo on its notepaper. There is no doubt that SaSSHA considered it part of its responsibility to follow up peer review reports with trusts. In the case of the children's services peer review, the official with responsibility for this was Rob Willoughby, SaSSHA's children's lead. SaSSHA would contact trusts to satisfy itself that recommendations in peer review reports were being implemented. Dr Myers told the Inquiry that she would expect to be told if there were matters of urgent concern arising out of peer review reports.[70]

West Midlands Strategic Health Authority

General initial approach

8.64 Following the reorganisation, as indicated above, the intention was for the SHAs to step down from their function as a performance manager in favour of the PCTs, who would fulfil this role through the commissioning process. Cynthia Bower told the Inquiry that PCTs were expected to drive improvement through monitoring contracts with providers, with those contracts informed and led by local clinicians involved in PCT governance, and by engaging local clinicians generally in service improvement and change. SHAs had the role of developing PCTs' capacity to undertake these duties. According to her, it was central to the SHA's role in quality improvement to do this and to promote the readiness of NHS trusts to obtain FT status.[71]

8.65 Cynthia Bower said that while SHAs were expected to provide oversight of the NHS in their areas, they were not expected to proactively assure themselves of the quality of care if they were unaware that problems existed:

68 Myers T100.12
69 Myers T100.13–14
70 Myers T100.71–72
71 Bower WS0000020976, paras 11–12

The WMSHA was required to maintain oversight of the NHS in their area. However, SHAs were not expected to proactively assure themselves of the quality of care on a service by service basis (for example by inspections, or direct observation of care) where no issues of safety apparently existed. Nor were they resourced as if this were their role ...[72]

The emphasis was ... on the SHA pulling back from their previous more detailed control over their organisations and a detailed level of knowledge. The tenor of "Commissioning a Patient Led NHS" was that these responsibilities would pass to the PCT.[73]

8.66 As she herself accepted, PCTs had been bound to face challenges in undertaking this task:

One of the difficulties ... is that the providers are the masters of activity information and they have much better knowledge about what is being provided. The providers therefore often knew far more about what was being commissioned from themselves than the PCT.[74]

8.67 To assist PCTs overcome this information deficit, a Commissioning Business Service Agency (CBSA) was set up by the WMSHA to provide information on finances and the activities PCTs were commissioning.[75]

8.68 Peter Blythin confirmed the more active and detailed role of PCTs after the merger:

PCTs are responsible for entering into contracts with providers to commission services for their local population ... The PCTs were therefore, responsible for the quality of the service and care provided under that contract. That was their primary function.[76]

8.69 Quite how PCTs were supposed to undertake this role was less than clear. Eamonn Kelly thought that there was:

... a lack of clarity as to what "strong commissioners" looked like.[77]

8.70 It was clear at the time that PCTs needed assistance in their development. To that extent, the WMSHA gave them support in making executive appointments and putting in place programmes for "aspirant chief executives" and "aspirant directors" to develop key people to ensure PCTs were fit for purpose.[78] The continuous process of change in organisation and

72 Bower WS0000020977, para 14
73 Bower WS0000020982, para 27
74 Bower WS0000020986, para 38
75 Bower WS0000020986, para 39
76 Blythin WS0000019642, para 19
77 Kelly WS0000021701, para 17
78 Kelly WS0000021702, paras 21–2

function undergone by PCTs during the relevant period is considered in *Chapter 7: Commissioning and the primary care trusts*. For present purposes, it suffices to refer to the following statements:

- William Price, Chief Executive of SWSPCT from 2002 to 2006:

 As far as I can remember we didn't have anything routine and structured in place to comprehensively monitor the quality of services provided by the Trust. There was no external pressure applied on us as a PCT to carry out this role and I do not believe that quality monitoring was ever discussed as being part of our role when we were first established. As Chief Executives we knew that targets were the priority and if we didn't focus on them we would lose our jobs.[79]

- Geraint Griffiths, a Locality Director of South Staffordshire PCT (SSPCT) from November 2006 to July 2009:

 Given the significant scope of the role, and the need to establish the PCT from the legacy organisations, much of the first six months was taken up with immediately necessary tasks, and carrying out a risk assessment of priority areas for the future. At the point of me joining the PCT in November 2006, there were no directorate staff in place, and a significant time commitment was spent supporting the over 200 commissioning staff through the PCT transition and starting to appoint them into substantive roles, or supporting them into other roles in the NHS.[80]

- Yvonne Sawbridge, SSPCT Director of Quality from November 2006:

 In 2006 there was clear policy intent to develop the role of commissioners. This included broadening out the measurement of quality from Key Performance Indicators to measures more relevant for patients. However, there was no road map that set out how a PCT could do this and no agreed national indicators.[81]

 Q. … you effectively say you were starting with a blank sheet of paper.

 A. Well, that's certainly how it felt to me on the ground. It was around taking the policy statements around improving commissioning and developing that framework and turning it into a work programme, and World Class Commissioning did that well. But it was October/November 07 before we got that very clear route map about the type of – of competencies that a PCT needed to have and how to demonstrate those as good commissioners.[82]

79 Price WS0000016114–15, para 47
80 Griffiths WS0000014860, para 38
81 Sawbridge WS0000013395, para 20
82 Sawbridge T64.21–22

It is obvious therefore that the resource at my disposal reflected the understanding that whilst our organisation had a real part to play in monitoring quality issues, it needed to place reliance on other regulators work in this regard in order to fulfil its role.[83]

8.71 The conclusion drawn in *Chapter 7: Commissioning and the primary care trusts* is that at no point during the period under review were PCTs equipped to meet the expectations with regard to the performance management of quality as described by SHA leaders.

8.72 In a briefing to the WMSHA Board in July 2006 concerning her vision for the future, Cynthia Bower was recorded as saying:

As part of the Intermediate tier, the SHA are paid to intervene for improvement. This covers a wide spectrum ranging from advice and support to stepping in when things appear to be a matter of concern. However, this is not as observers or commentator on the system, but to actively intervene for improvement.[84]

8.73 The WMSHA emphasised at an early stage the importance it attached to listening to the patient voice. However, it was clear from Ms Bower's answers to questions put by the Inquiry about how this was put into practice, that the various measures taken to consult the public and obtain their views about quality of care were much more concerned with the formulation of future plans rather than seeking their views on the quality of care being offered by particular providers.[85] Indeed, she made it clear that it was not the responsibility of the SHA to ensure that safe care was provided, but to intervene if matters of concern emerged:

We did not set out specifically, as part of this, to understand at a trust level or at an individual ward level, for example, that very detailed level of care, and the experience of care that an NHS organisation itself was supposed to do. What we were saying in doing this was to say, we aren't just going to be an organisation ... that is there for [sic] *– to represent and to be a champion for the NHS trusts and the PCTs on our patch. It's also part of our responsibility, as it's part of the responsibility anyway – of anyone anywhere in the system to try and understand what the patients and the public are saying ...*[86]

83 Sawbridge WS0000013397, para 27
84 CB/5 WS000021244–45; Bower T73.52–53; T73.62–63
85 Bower T73.61
86 Bower T73.61–62

> [A]*s a small strategic organisation ... that was trying to make judgements about where to be proactive and demonstrate what good care should look like and try and be reactive and deal with problems, we were going to intervene. We didn't see ourselves as – as such a distant organisation that if there were problems in the patch we didn't think it was our job to try and resolve them ...* [W]*e did see it as our job to intervene when we thought that trusts or PCTs were not themselves tackling the problems that needed to be tackled.*[87]

8.74 For example, she was adamant that it was not the job of an SHA to intervene on matters such as safe staffing levels, having neither the capability nor the capacity to do so.[88]

The development of quality and patient safety in region

8.75 In December 2006, the then Chief Medical Officer, Professor Sir Liam Donaldson, published a report, *Safety First: A report for patients, clinicians and healthcare managers*.[89] This observed that insufficient use was being made of nationally collected incident reports and that:

> *... while progress has been made, patient safety is not always given the same priority or status as other major issues such as reducing waiting times, implementing national service frameworks and achieving financial balance.*[90]

8.76 A number of recommendations were made to improve patient safety, including a requirement that PCTs should be accountable for ensuring that all providers had effective patient safety systems and were implementing technical solutions satisfactorily. Erroneously, Mr Peter Blythin, WMSHA's Director of Nursing and Workforce, interpreted this recommendation as meaning:

> [It] *clearly refers to the PCTs. It essentially states that when PCTs commissioned services, they had to assure themselves that those services were safe.*[91]

8.77 Yvonne Sawbridge of SSPCT understood it differently:

> *We would actually be confirming whether our providers had a reporting system in place as opposed to assessing the effectiveness of that system.*[92]

87 Bower T73.62–63
88 Bower WS0000020988, para 45; Bower T73.64
89 OI00020000060 *Safety First: A report for patients, clinicians and healthcare managers* (15 December 2006), Department of Health
90 OI00020000067 *Safety First: A report for patients, clinicians and healthcare managers* (15 December 2006), Department of Health, p 6
91 Blythin WS0000019647, para 41
92 Sawbridge WS0000013411–2, para 78

8.78 Following this report, Dr Shukla and Mr Blythin set out the WMSHA's approach in a report to the Board in January 2007.[93] Among the measures they proposed were:

- A Patient Safety and Quality Group to lead the establishment of an overarching framework for the SHA on clinical governance and to "give the appropriate assurances to both the Board and the Audit and Risk Committee regarding the Authority's responsibilities for patient safety";[94]
- Action to improve organisations' performance on the HCC annual ratings within NHS West Midlands;[95]
- The WMSHA's performance and clinical governance teams were to review and feed back to organisations on their action plans for improving their HCC quality ratings;[96]
- Development of a plan to improve performance relating to healthcare acquired infections (HCAIs) in the region;[97]
- Development of a set of quality metrics with the NHS Institute for Innovation and Improvement, with a view to their adoption by all 10 SHAs.[98] In seeking to develop such metrics for incorporation into commissioning contracts, the WMSHA was the first SHA to devise a plan to do this.

Patient safety and quality group

8.79 Among other activities for which the group was responsible were management of the response of the SHA to SUIs, coordination of work on incident reporting and learning, and response to suicides and homicides related to the provision of health services.

8.80 The membership included Dr Shukla and Peter Blythin, along with the Head of Performance, and members of the Patient Safety Action Group, who had been transferred from the National Patient Safety Agency (NPSA) to the SHA. From September 2007, the regional representatives of the HCC were also invited to attend.[99]

Development of quality metrics

8.81 The quality and patient safety metrics that the WMSHA was developing with the NHS Institute for Innovation and Improvement were intended to be developed on the themes of:

- *Patient safety – for example avoidable deaths, healthcare associated infections, medication errors, falls, wrong site surgery;*

93 RS/1 WS0000018575
94 RS/1 WS0000018577
95 RS/1 WS0000018578
96 RS/1 WS0000018578
97 RS/1 WS0000018579
98 RS/1 WS0000018579
99 Blythin WS0000019648–9, paras 42–7; Shukla WS0000018534, para 21

- *Patient feedback – designed to ascertain involvement of individual patients in their care, treatment with dignity and respect, acceptability of the environment including food;*
- *Patient experience – for example prevalence of pressure sores, number of patient moves during inpatient stay, re-admission rates;*
- *Efficiency measures for both providers and commissioners relating to Better Value Better Care productivity indicators.*[100]

8.82 Thus, WMSHA was clearly intending to increase the focus on patient safety by seeking means of measuring how safe the services being provided in the region were; not by reference to process-driven targets but by actual results of poor treatment and care, taking account of patients' own experience. In addition, Dr Foster Intelligence had been commissioned to work on the development of quality metrics for commissioners. These were expected to enable PCTs to monitor the quality of the care they commissioned, and the WMSHA to review commissioning decisions.

8.83 The intention, during the course of 2007, was that PCTs would incorporate quality metrics into agreements with their providers from April 2008, having used them in "shadow" form during the previous year.[101]

8.84 The willingness to use the services of Dr Foster Intelligence shows that the WMSHA had no general objection to this organisation even though, as can be seen in *Chapter 5: Mortality statistics*, it was highly reluctant to accept the adverse inferences capable of being drawn from its HSMR ratings.

8.85 The development did not go as planned. Metrics do not appear to have been available in a usable form before about November 2007, which was later than envisaged.[102] In that month, Dr Shukla and Mr Blythin reported to the Board that Dr Foster Intelligence, which had been commissioned in September 2006, had produced eight metrics that had been agreed in consultation with a working group containing clinical and analytical staff from the WMSHA, PCTs and provider trusts. These included:

- Time to surgery for elective procedures;
- Time to surgery for selected emergency procedures;
- Re-admission rates for orthopaedic procedures;
- Excess bed days;
- Day case rates for selected procedures;
- Ethnicity recording.[103]

100 RS/1 WS0000018579; Shukla WS0000018542–3, para 49
101 Shukla T69.33–34
102 Shukla T69.35–6
103 RS/10 WS0000018726

8.86 Most of these measures either were focused on access to treatment, or were at best indirect measures of the standard of care. For example, it was said that re-admission for orthopaedic procedures "may indicate poor clinical practice or aftercare", and excess bed days "may be an indication of patient complications".[104] It seems unlikely that such metrics would be as direct a measure of poor care as medication errors and avoidable deaths, assuming that a reliable analysis could be developed. The report gave no explanation as to why the original list of proposed metrics had been changed.

8.87 Two indicators relating to hospital mortality had been planned but were being "revised" in connection with the work that had been commissioned from Birmingham University, in connection with high HSMRs at the Trust and elsewhere in the region.[105] As is shown in detail in *Chapter 5: Mortality statistics*, it is clear that WMSHA was less than convinced of the reliability or desirability of the HSMR method used by Dr Foster. The result was that throughout 2006 and 2007, there was an acknowledged gap between what was realised was required by way of metrics to monitor patient safety and what was available. Dr Shukla told the Inquiry:

> *The expectation was that PCTs, as commissioners of care, needed to have some way of knowing what the quality of care is being provided. There were no nationally determined metrics or quality measures at that time. The ... national contract at that time was – well, silent on these issues completely. There was no expectation. The world has moved on quite radically since then. So the ... contract, which was published in 2006 was ... finance and activity-based contract, very little on quality. As part of that we ... felt in the SHA we should do some work to support the PCTs in their role as commissioners of quality of care, and so the initial work was done to determine which metrics would be useful. Then that piece of work's passed on to the PCTs ... and the CBSA* [Commissioning Business Support Agency] *for that work to be undertaken by the CBSA for PCTs. The CBSA ... board ... would drive the work to be done for the PCTs. My recollection ...* [is that] *... it took longer than anticipated for those metrics to be available until later that year.*[106]

8.88 While this developmental work was going on, there was no effective contact between the Patient Safety and Quality Group at the WMSHA and PCTs to monitor their focus on quality issues.[107] Dr Shukla explained to the Inquiry that, until their fitness for purpose had been assessed through the World Class Commissioning project, PCTs were still, themselves, in a developmental stage and there were very limited tools available to them for commissioning for the quality of service provision.[108] Asked whether that meant that, in the meantime, they just had to hope that good quality and safe care were being delivered, Dr Shukla's evidence

104 RS/10 WS0000018728–9
105 RS/10 WS0000018726
106 Shukla T69.36–37
107 Shukla T69.38
108 Shukla T69.38–39

was that the system relied on trust boards knowing what was happening in their organisations clinically:

> *There was a high degree of trust that the boards would be looking at quality of care. Safety First had been produced in December 2006, which talked about the role of the board. So there was a kind of a general acceptance and expectation that things would be permeating through to individual organisations and that they would be acting on something like Safety First, that organisations would be looking at their own services they're providing, boards of organisations would be fully sighted on what's happening in their ... respective clinical areas. That was the expectation at the time.*[109]

8.89 Eamonn Kelly, the WMSHA Director of Commissioning and Performance, had anticipated that metrics would be used in the 2007/08 contracts and was disappointed to learn that they had not been. He also made it clear that the system relied on trust:

> [T]*he expectation in the system was one of trust, that if people made a commitment to do something at that level that they would do so.*[110]

8.90 As far as the SSPCT was concerned, it did include quality metrics in its contract with the Trust for 2008/09, but by this time the HCC investigation had already started.

8.91 In the absence of the sort of tools that Dr Shukla and her colleagues were seeking to develop, and in the context of the observation in *Safety First* that insufficient attention was being paid to safety, reliance on trust was not fully justified, but it may well be that, in terms of a systemic approach, there was little else an SHA could do. However, this acknowledged gap between what was needed and what was available to monitor quality and safety should have led to an appreciation of the critical importance of looking for, and not ignoring, warning signs of the type described in *Chapter 1: Warning signs*.

Serious untoward incident reports

8.92 As noted above, at the time of the merger, Dr Shukla was informed by Dr Myers that the SHA was struggling to deal with its duties in relation to SUI reports and management. This situation was not improved by the reduction in staff available to the WMSHA. Dr Shukla told the Inquiry:

> *We struggled to keep up with the SUIs, there's no doubt about that, because ... having an organisation of 75 people doing all of the things ... that were required ...*

109 Shukla T69.43
110 Kelly T75.51

Q. So the reorganisation seems to have led in this case to there not being enough staff for a time at the SHA considering serious untoward incidents?

A. It would be probably true for the fact that in terms of the capacity across the whole of the patient safety team ... the level of interrogation and detail that we could do would have been not as robust as it would have been in the old previous SHAs with their teams. Each of the three SHAs had teams looking at this. Whereas the new SHA had a relatively small amount of resource.[111]

8.93 In January 2007, Dr Shukla and Mr Blythin produced an SUI reporting policy and procedure.[112] This defined what an SUI was and prescribed what the WMSHA should do:

- Once a trust had determined that an SUI had occurred, it was to notify the SHA immediately via a website. A summary of the SUI and immediate actions taken was to be included in the entry within 72 hours.[113]
- Trusts and PCTs should record all contact with the SHA or other organisations on the incident form.[114]
- A member of the SHA's Patient Safety and Quality Group was to scrutinise all SUIs and decide on the action to be taken, which might include advising the trust that a follow-up report would be required or that there should be a review in a month, and again at two and a half months, with a view to closing the incident within three months.[115]
- The SUI would be registered as "closed" when the incident investigation was complete, the trust or PCT had confirmed that an action plan had been developed and a summary of this and the key lessons learnt had been recorded on the system.[116]

8.94 On arrival at the WMSHA, SUI reports were distributed to a number of officials responsible for patient safety and clinical governance issues, including Dr Myers and Mr Blythin. Allocation was in accordance with area of responsibility. The recipient, at their discretion, could enter a "red flag" where it was thought that the individual incident merited the attention of the Patient Safety and Quality Group.[117]

8.95 FTs were not obliged to report their SUIs to the SHA at all. The SUIs were, instead, to be monitored by the PCTs, which were, in turn, meant to keep the SHA informed by submitting a report on the UNIFY performance database.[118] However, there were technical issues that prevented PCTs from accessing the relevant system, so that, while they could input information about an SUI onto the database, the PCTs could not then edit or update the

111 Shukla T68.79–81
112 RS/2 WS0000018610
113 RS/2 WS0000018619
114 RS/2 WS0000018619
115 RS/2 WS0000018620–1
116 RS/2 WS0000018618
117 Blythin T70.57–58
118 RS/2 WS09000018615

information they entered, nor could they see any information entered by a trust. The PCT would, therefore, be reliant on the WMSHA informing it that a trust had reported an SUI.[119]

8.96 Certain "never events" were followed up either directly with the relevant trust by a senior member of WMSHA staff or by delegating this to the commissioning PCT. These included incidents of a recurring nature; incidents subject to NPSA safety alerts; and alleged homicides by mental health patients. Apart from these events, it was quite possible for SUIs not to be followed up at all. However, Dr Shukla did not accept that once the new SHA had been established for a year or so its role in managing SUIs was hindered by any lack of capacity.[120]

8.97 The weakness in the WMSHA system for handling SUIs was highlighted at the Inquiry by the evidence concerning the SUI report in the case of Mrs Astbury, as described in *Chapter 1: Warning signs*. Put simply, the incident report was received but not followed up. Mr Blythin accepted that it was a particularly serious event:

> *That would have been an incredibly alarming SUI, actually, because it was fundamental about (a) teamwork, about the relationship between doctors and nurses, about the leadership on the ward, about individual practitioners. It would have been quite systematic about medicines management. So there would have been a whole series of things that would have come out of there to ask the question to the Trust. All SUIs as you probably know, Mr Francis, we follow through with a root-cause analysis what happened, and I think the detail of that root-cause analysis would have then examined individual practitioners and all those points I've just gone through. So it would have been a very serious untoward incident. It obviously had very tragic results for the patient.*
>
> *What also would have been interesting to follow-up in trends and learning lessons would have been what the outcome of the coroner's inquest would have been, because, again, there would have been more detail* [to] *come out about individual practitioners. So I think that – that was an opportunity missed.*[121]

8.98 Although various SUIs were discussed at the Patient Safety and Quality Group, this one was not among them. There was no evidence, in spite of specific investigation for the Inquiry, that any action was taken by the WMSHA on this SUI from June 2007 until January 2010, despite it having been "red flagged".[122]

8.99 The failure to take action in this case was not an isolated instance. On assuming responsibility for patient safety in January 2010, Mr Blythin reviewed the SUIs and found that they had not been routinely closed from 2007 to 2010. He told the Inquiry that, as at January 2010,

119 Shukla WS0000018538, para 33
120 Shukla T68.82
121 Blythin T70.58–59
122 WS0000024997, *Log of events regarding Serious Untoward Incident Number: 2007/5318* (prepared for the Inquiry by WMSHA, 15 April 2011); Blythin T75.4

"thousands" of SUIs had not been closed.[123] The Astbury case was among them. On 22 March 2010, the WMSHA "closed" this case, although it had not received the Trust's report or action plan and the inquest had yet to be held.[124]

8.100 External confirmation of the lack of effective SUI management by the WMSHA came from Trudi-Anne Williams, the former Head of Governance at the Trust, who was asked whether she was surprised at no action having been taken in the Astbury case:

> *[N]o, it doesn't surprise me because we weren't chased for action plans, we weren't chased for reports once it was reported on to the STEIS system. It was only much later that that started to happen, once the Healthcare Commission actually came in and started to do their investigation and the findings of their report were known, and ... suddenly we had to supply lots of information, whereas previously that had not been the case.*[125]

8.101 It would be unfair to allocate responsibility to any individual on the necessarily speculative evidence before the Inquiry, but the failure to take any action on the Astbury case, in itself a very serious incident showing up many of the alarming deficiencies at the Trust, should not have occurred in an effectively run SUI system that is dedicated to the protection of patients from the recurrence of such incidents. That it was not effectively run was confirmed by the state of affairs discovered by Mr Blythin.

Performance management from 2006 to 2007

8.102 Between July 2006 and August 2007, Jonathan Lloyd was Head of Performance at the WMSHA. Initially, he reported to Eamonn Kelly, Director of Commissioning and Performance, but from December 2006 he reported directly to the Chief Executive, Cynthia Bower.[126]

8.103 Part of Mr Lloyd's role was to monitor acute trusts' performance against non-financial targets. Safety alerts, SUIs and surveys would not generally be considered by the performance management team. Matters relating to the quality of care as such were considered to be the responsibility of Peter Blythin and Dr Shukla.[127] The performance management team also fed into the SHA's implementation of the PCT Fitness for Purpose programme.[128]

8.104 Mr Lloyd reported to WMSHA on a monthly basis on the performance of organisations in the region. Information on performance against national targets was analysed and presented by PCTs regionally, rather than by reference to individual provider organisations. He was looking at the information emanating from initially 30 then 17 PCTs, and 25 acute trusts, and a key

123 Blythin T70.65–66
124 WS0000025000, *Log of events regarding Serious Untoward Incident Number: 2007/5318* (prepared for the Inquiry by WMSHA, 15 April 2011)
125 Trudi-Anne Williams T133.22–23
126 Lloyd WS0000022343, para 5; Kelly T75.37
127 Lloyd WS0000022344, para 9
128 Lloyd WS0000022344–5, para 10

part of his role was liaising on target performance with the DH.[129] Where organisations were not meeting targets, they were approached for information on their plans and the proposed action to remedy the situation. He had access to programme specialists and an "intensive support" team at the DH to assist in addressing organisations that appeared to be failing in relation to their targets. However, there was access to less "soft intelligence" than he had been accustomed to in his previous post at BBCSHA, where it had been possible to foster closer relationships with staff in local organisations. This was also, he said, a result of the move away from direct performance management to management via PCTs.[130]

8.105 By and large, the Trust's performance against national targets did not distinguish it adversely from other trusts in the region, and, consequently, no concerns were raised for the performance team arising out of this monitoring.[131] In so far as issues arose at the Trust in relation to performance, for instance with regard to A&E, the PCT was expected to engage with the Trust directly while the WMSHA supervised the PCT, applying only a "light touch".[132] In the case of A&E, this manifested itself in Mr Lloyd writing to both the Trust and the PCT asking the latter to indicate whether it was content with the Trust's action plan and to confirm how they were to performance manage implementation jointly with the Trust.[133]

8.106 Mr Lloyd said that any monitoring of patient experience by the WMSHA was "minimal" as this was considered to be the responsibility of the trusts or patient involvement organisations.[134]

8.107 In October 2007, Mr Lloyd left the WMSHA and Steve Allen was appointed Director of Performance and Information, taking over the performance management function.[135] He found the performance management team short-staffed, with only two full-time managers, one of whom had left shortly after his appointment, and various other vacancies that were unfilled. He provided a note containing his proposals for change to the Chief Executive shortly after his arrival:

> 1. *Strengthen the PM team: The team is small and weak. Some of the members don't want to be here and should be supported to move on ...*
> 2. *Introduce some process: Linked to 1, but we need to get some basic processes to work urgently ...*
> 3. *Integrate Intelligence: We currently aren't very good at integrating performance information, particularly in relation to soft intelligence ...*

129 Lloyd WS0000022345, para 12
130 Lloyd WS0000022348, para 20
131 Lloyd WS0000022352–3, para 33
132 Lloyd WS0000022354–56, paras 38–41
133 Lloyd WS0000022355, para 40; JL/5 WS0000022493
134 Lloyd WS0000022350, para 25
135 Allen WS0005000152, para 8

4. *Stop chasing events: The Performance Team spends a lot of time dealing with crises and urgent matters, and some of this is essential, particularly if SHA response is required nationally. However, I think we need to be more selective on those areas where we intervene. For example, I'm not convinced we ought to be intervening directly on Trust operational matters ... Instead, we should be requiring PCTs to respond.*[136]

8.108 He had not intended the note to be critical of the work that had been done before his appointment, but pointed to the challenge facing the WMSHA at the time:

> *... throughout 2006, when Jonathan Lloyd was ... doing the job, there was a constant dilemma. We used to use this phrase quite often about "holding on while letting go". And there was a dilemma about how big the performance team should be. If we made it too big, there would be this an inclination, I think, to, if you like, go over the heads of the PCTs and become ... kind of very, very operational. If we made it too small, then the risk was that we were leaving a gap in that the PCTs weren't at that stage ready to pick up the performance management mantle.*[137]

8.109 He was surprised at the amount of time SHA officials were spending on crisis management:

> *... certainly it didn't feel very strategic at the time, and there were a huge number of issues that were just floating around in the SHA. Ambulance turnaround was one of them. And I felt that we were taking upon ourselves an impossible task – to ... constantly say "We can't trust the PCTs to do this, so we're going to have to do it".*[138]

Performance management from 2007 to 2009

8.110 Until he was able to recruit more staff, Steve Allen's team continued the previous practice of monitoring performance against national and local targets. In addition, attention was paid, at Cynthia Bower's insistence, to concerns across the region about healthcare infection, issues with the ambulance service and the linkages between hospital and community care in North Staffordshire.[139]

136 Allen WS0005000162, para 48; STA/7 WS0005000271–2; T71.16–17
137 Allen T71.19
138 Allen T71.22
139 Allen T71.27–29

8.111 In October 2007, the WMSHA published a performance management framework.[140] This described the role of the SHA as follows:

> *The SHA is responsible for ensuring that the health system within our area operates effectively and acts to drive improvements in equity, quality, safety, responsiveness and efficiency of services. One of the primary means we have to influence the system is* ***performance management****: that interconnected set of activities in which we measure, monitor, challenge and target aspects of an organisation's performance in important areas of healthcare delivery.*[141]

8.112 Because of the size of the organisation, it would have to target its resources:

> *The SHA is a small organisation with performance management responsibilities currently for 39 organisations. An approach to performance management which systematically focuses on areas of highest risk is the most effective use of our resources.*[142]

8.113 It was recognised that performance management required more than the examination of national targets and finance:

> *Performance management needs to develop beyond the core of "national targets and finance" to encompass wider concerns like health inequalities, quality of care and issues of organisational governance.*[143]

8.114 However, the means of achieving this were still regarded as being via the exercise of responsibility by trust boards, and the increased role of PCTs.

8.115 It was proposed that the SHA would identify risks by a rating system. The risks to be identified in relation to quality and outcomes were largely those of not meeting either national or local targets, thereby continuing the regional emphasis on a target-driven culture.[144] If this approach to assessing risks in relation to the quality of care was to extend from access and process targets, such as waiting times, to quality outcomes, this would have to be achieved by the setting of quality requirements and metrics in the commissioning arrangements between PCTs and provider trusts.

8.116 There was also to be a measurement of "governance risk", ie the risk posed by an organisation's systems, processes and competences, using evidence derived from formal developmental processes such as FT development projects, self-assessment and other

140 STA/6 WS0005000252
141 STA/6 WS0005000254 (emphasis in original document to para 8.111)
142 STA/6 WS0005000254
143 STA/6 WS0005000254
144 STA/6 WS0005000262–4

evidence. The areas to be covered included clinical quality and safety, and patient experience.[145]

8.117 Trusts would be rated "red", "amber" or "green". "Green" trusts would receive little attention, "amber" ones limited requests for information, and only "red" trusts would be subjected to formal review processes.[146]

8.118 During the period under review, PCTs had not developed their quality requirements in the commissioning process to any great extent. Therefore, the role of the WMSHA in performance management was still developing by the time the Trust achieved FT status in February 2008, and it is difficult to detect much practical difference in approach from what had been done under Jonathan Lloyd's management. In so far as it went beyond monitoring targets, the WMSHA relied largely on self-assessment or a matter of serious concern being brought to its attention.

The approach to financial performance management

8.119 SHAs did not fund provider trusts directly. The principal source of funding for them was via the commissioning arrangements with PCTs from monies allocated by the DH. Each SHA received a separate allocation from the DH for its own running costs, and for education and training in the region. SHAs instead had the role of providing oversight of the financial and non-financial performance of organisations within their regions, including provider trusts and PCTs, on behalf of the DH. Each year, a regional budget or "control total" would be agreed between the DH and each SHA, and it was the duty of the SHA to ensure that this budget was not exceeded in the region.[147]

Shropshire and Staffordshire Strategic Health Authority

8.120 Philip Taylor, formerly SaSSHA's Director of Performance and Finance, told the Inquiry that the obligation set by the DH was to achieve a financial balance across the area. Therefore, if one trust was in deficit, this had to be made up from the resources otherwise available to other trusts in the area. There was little scope allowed to move from this requirement:

> *In terms of negotiating the control total, there can be a dialogue and perhaps some minor movement, but not much.*[148]

8.121 SaSSHA would examine closely the monthly financial returns received from trusts. SaSSHA would also check the overall monthly financial performance, compliance budget plans, PCT

145 STA/6 WS0005000264–5
146 Allen WS0005000167, para 60; STA/6 WS0005000264
147 Shanahan WS0000020500–1, paras 14–17
148 Philip Taylor WS0005000426, para 8

spending assumptions and the current forecast year-end surplus/deficit. There was no consideration by the finance staff of the impact of finances on the quality of care.[149]

8.122 The emphasis on financial control has to be seen in the context of the requirement of the then Secretary of State, Rt Hon Patricia Hewitt MP, for the year 2005/06 that the overspend in the previous year be corrected and that each organisation's accounts be brought into balance. The Secretary of State had written to the chairs of all trusts with deficits, and Sir Nigel Crisp, NHS Chief Executive and Permanent Secretary at the DH at that time, had on 28 June 2005 written to all trust chief executives. He expressed himself in unequivocal terms:

> *This year's planning round is particularly important. We will not accept local delivery plans that forecast deficit, or are underpinned by unrealistic assumptions.*[150]

8.123 Sir David Nicholson told the Inquiry that:

> *This letter reflected the fevered environment that existed in the NHS at that time, given the scale of debt that was mounting up. Every day one would pick up a newspaper that read "NHS in Crisis".*[151]

8.124 Antony Sumara, then Managing Director of SaSSHA in its transition to WMSHA, wrote to all chief executives within the area under SaSSHA's oversight in October 2005, referring to the need to restart work-reduction programmes, although emphasising that:

> *These measures are not about compromising clinical services. Indeed, they are about improving productivity and clinical care to patients.*[152]

8.125 He emphasised the importance of controlling the pay bill:

> *It is vitally important over this period that control over your paybill is exercised and as a part of this, during October each trust and PCT will be expected to revisit their workforce plan with a view to restating this, in most cases, as a headcount reduction programme. The SHAs will then agree target reductions for each organisation on a quarterly basis up to 2007/08.*[153]

149 Philip Taylor WS0005000426–7, paras 10–11
150 DN/12 WS0000068078
151 Nicholson WS0000067659, para 96
152 DN/13 WS0000068083
153 DN/13 WS0000068083

8.126 He demurred from the suggestion that this amounted to exerting pressure, saying that any guidance would have been a matter of "suggestions to consider, as opposed to aggressive directions".[154]

West Midlands Strategic Health Authority

8.127 The actual financial performance of trusts and PCTs (but not FTs) was scrutinised by the WMSHA, and through it by the DH. Each trust and PCT made monthly returns ("FIMS reports") to the WMSHA. These would be examined to see if there was a projected surplus or deficit for the year end and a report was made to the DH. While this scrutiny was regular, it was not close: the sole concern of the WMSHA performance team was to monitor whether an organisation was within its budget. The integrity and accuracy of the accounts were a matter for the auditors appointed by the Audit Commission. The WMSHA would concern itself with the detail of the spending only if it appeared that a trust was not going to meet its budget commitments.[155]

8.128 This somewhat formulaic approach to the scrutiny of trust finances extended to the oversight of cost improvement plans (CIPs). Peter Shanahan explained to the Inquiry that CIPs were intended to improve the efficiency and productivity of an organisation and were not meant to be simple "cuts" in expenditure.[156] As such, trust finance directors were not responsible for proposing how a CIP percentage would be achieved. This was a matter for the operational managers:

> *A trust's Finance Director is not responsible for determining how such efficiencies should be achieved. A Finance Director must utilise the organisation's operational managers to look at their respective teams and identify ways in which the organisation as a whole can save costs and improve efficiency.*[157]

8.129 Similarly, the WMSHA would not look at the detail of the proposed CIP unless there was an obvious illogicality in it.[158] It would merely satisfy itself that the trust was on track to meet its end-of-year budget. Ms Bower said:

> *I would not look at how a trust was meeting its CIP, I would simply look at whether it was on track each month in terms of Income and Expenditure balance. It was the duty of the Trust to ensure that it was not meeting its CIP at the expense of the quality of care that it was providing.*[159]

154 Sumara WS0000005914, paras 18–19
155 Shanahan WS0000020500–2, paras 17–19 and 22–3
156 Shanahan WS0000020504, para 31
157 Shanahan WS0000020504, para 32
158 Shanahan WS0000020504–5, para 34
159 Bower WS000002100–1, para 86

8.130 Therefore, it was unlikely that the scrutiny of the finance team, either at trust level or at the WMSHA, would uncover any adverse implications for patient safety contained in a CIP.

Interaction with the primary care trust

8.131 Susan Fisher, Finance Director of SWSPCT, complained to the Inquiry that Philip Taylor had been intimidating in his approaches to her organisation over the need to resolve the deficit. She alleged that Mr Taylor wanted immediate repayment of SWSPCT's historic deficit. Ms Fisher said that her view was that this could not be done without "decimating" care. She stated that she was put under significant pressure by Mr Taylor to cut costs and hit targets. She told the Inquiry:

> *... there were often telephone calls on Friday evenings at home asking me for up-to-date figures and forecasts. It is safe to say that I did on occasion feel intimidated by members of the SHA and was put under a lot of pressure to hit the targets.*[160]

8.132 In her oral evidence, she clarified that this statement referred to Mr Taylor, and that his behaviour permeated the rest of the WMSHA's financial team. It was not the timing of his calls that distressed her but their manner and content. She was visibly distressed while giving her evidence on this topic.[161] She gave an example of what she claimed to have experienced:

> *THE CHAIRMAN: Was the language used threatening or was it just the manner and frequency?*
>
> *A. You know, people at that level in the NHS have a very high level of emotional intelligence in the way they talk and behave. I mean, that's part of how ... you're expected to display that behaviour. But just one example is ... I was asked to start to consider planning a career outside the NHS, you know. ... if you took that sentence in isolation, that could be seen by somebody who was mentoring me or trying to move me on, but when the previous conversation was about not making sufficient moves, in payback of the deficit to be followed by that statement, is perceived very differently. And when you're working very hard, as I believed I did, and I believe my board would say I worked tirelessly on financial position and with GPs to try and make sustainable solutions for Staffordshire, that's quite an intimidating phone call on a Friday night, when actually, you do, as much as you can, try and switch off on a Saturday and Sunday to recharge your batteries, and I believe that was in his mind at the time when he rang me.*[162]

8.133 Mr Taylor denied that he had ever harassed or bullied Ms Fisher. He accepted that there was a considerable focus on removing the deficit at the time but had no recollection of contacting

160 Fisher WS0000042304–5, para 33
161 Fisher T96.45–48
162 Fisher T96.48–49

her out of office hours. He pointed to certain apparent factual inaccuracies in the detail of her evidence.[163]

8.134 Mike Brereton, when asked about this matter, considered it would have been completely out of character for Philip Taylor to behave in the way described, although he did recollect that he had a habit of telephoning people from his car on the way home. He accepted that there may be a difference between the actuality of a person's behaviour and how it may be perceived.[164]

8.135 The evidence does not establish to the Inquiry's satisfaction that Philip Taylor or his department indulged in bullying or harassment, whether intentional or unintentional. What it does establish is that there was a fraught and tense atmosphere between a number of senior officials grappling with the difficulties of the requirements imposed on them to correct the deficit. Ms Fisher was genuinely distressed by calls, which may well have taken place outside normal office hours, in which some implication was conveyed regarding her career should the desired financial correction not be achieved. Robust conversations are likely to take place in the circumstances facing the NHS at the time and not all of them are likely to have been pleasant. While no grounds for personal criticism of Mr Taylor can be drawn from this episode, the pressure on all concerned that it illustrates was undoubtedly a significant part of the culture pervading the entire system at the time. This played its part in the focus on finance, at the expense of the necessary parallel focus on quality.

Shropshire and Staffordshire Strategic Health Authority's interactions with the Trust

8.136 The evidence is somewhat equivocal about what the leadership of SaSSHA thought about the Trust throughout the period until the merger.

8.137 Mrs Brisby told the first inquiry that when she was approached to consider applying for the post of Chair at the Trust, she was informed by Mr Brereton that it was a "failing" trust. This point has been considered in *Chapter 2: The Trust*. She gave evidence to the Inquiry, and it is accepted, that she was told by Mr Brereton that the Trust was suffering from poor governance and financial difficulties.[165] While she may not have been specifically told by Mr Brereton that this was a "failing trust" (he denied this),[166] it is likely that this was her understanding of what she was told.

163 Philip Taylor WS(2) WS0000056082–5, paras 13–16 and paras 21–3
164 Brereton T97.32–33
165 Brisby WS0008000003–4, paras 5–9; T129.7
166 Brereton T97.67

8.138 While Mr Brereton did not recollect saying that the Trust was "failing", he did accept that he had concerns:

> *I do not recall ever referring to the Trust as a "failing trust". It is the case, however, that I had a general concern that the Trust had been without a substantive Chair or CEO for some months ... and that this might have lowered morale amongst Trust staff ... It was not a failing trust in my opinion.*[167]

8.139 He could not remember being told of any concerns about the quality of care at the Trust, but he did consider it to be underperforming. In oral evidence to the Inquiry he said:

> *Our view of it was actually it should have been a high performing trust, and it should have been a high performing trust because it was medium sized. It wasn't a teaching hospital. It didn't have a large number of high technology processes. It didn't deal with really the high end of the case mix. That was done in other larger hospitals elsewhere. It was in relatively new buildings. It didn't have the sort of challenging population to deal with that, for example, the North Staffordshire has, you know, high levels of disadvantage. And that such a trust probably ought to be one which could perform very well. In all honesty, I think our disappointment was that it wasn't better than it was. That it was a relatively mediocre place.*[168]

The 2002 Commission for Health Improvement

8.140 The nature of the CHI report published in 2002 has been described in *Chapter 1: Warning signs*.[169] As quoted there, Professor Cumming accepted in retrospect that nursing levels had been low at the Trust for a long time. There was a wide range of concerns found, including the absence of effective clinical governance, low nursing staff levels and poor training. The Trust was required to produce a clinical governance development plan and annual report each year for review by the SHA.[170] However, this position appears not to have made any particular impact on Mike Brereton, who told the Inquiry:

> *The Trust faced a number of performance challenges during my period at SaSSHA ... but I do not recall that these challenges stood out by comparison with those faced by other acute hospital trusts, nor do I recall that the quality of care and/or patient experiences at the Trust had become a concern to SaSSHA staff or myself at this time.*[171]

167 Brereton WS0000037203, para 43
168 Brereton T97.37
169 HCC0016000107 *Report of a Clinical Governance Review of Mid Staffordshire NHS Trust,* (January 2002), CHI
170 IRC/20 WS0000017151
171 Brereton WS0000037197, para 25

8.141 He expanded on this in his oral evidence:

> *I have to say that in hindsight and with what we now know ... there has to be an acute anxiety that the appalling things that happened at some point in that Trust weren't – weren't obvious to us at that point. We were not conscious if those things were happening then, that they were happening. And none of the normal, both formal and informal, hard and soft indicators, from all sorts of sources that we would normally take note of, were ringing bells for us the* [sic] *that time.*[172]

8.142 This position is difficult to understand in the light of what was known at SaSSHA at the time of the CHI report. A 2004 SaSSHA briefing paper summarised the report as indicating that urgent action was required in respect of:

- Problems caused by high numbers of emergency admissions;
- The flow of patients from admission to discharge, appropriate and timely placement of patients and the minimisation of transfers between wards;
- Staff mandatory training;
- The need for a consistent organisational approach to embedding an open and learning reporting culture;
- Ensuring the consistent maintenance of patients' dignity and privacy to the highest possible standard;
- Ensuring that staff are aware of the outcomes of complaints and that information is disseminated to ensure learning across clinical teams and directorates.[173]

8.143 In addition to these points, the CHI report itself had noted issues around inadequate staffing and low staff morale at the Trust as evidenced by abnormally high sickness and absence rates.

8.144 In relation to staffing, the report stated:

> *Throughout the review CHI received reports of nurse staffing shortfalls, which were perceived to directly influence the ability to provide quality care. It was unclear to the staff interviewed whether the apparent shortage of staff was due to inadequate workforce planning, inability to recruit, financial restraints, or a mixture of all three. However, it was clear that staff in some areas are under almost constant pressure.*[174]

172 Brereton T97.36
173 IRC/20 WS0000017151
174 HCC0016000145, *Report of a Clinical Governance Review of Mid Staffordshire NHS Trust* (January 2002), CHI

8.145 The report made recommendations in relation to these concerns:

> *Urgent action is required to review skill mix in nursing areas and make appointments to vacant consultant medical posts.*
>
> *Urgent action is required to monitor levels of dependency in clinical areas and ensure a robust system for the redeployment of staff.*[175]

8.146 Mr Brereton told the Inquiry that this was known to SaSSHA, but, he said the same phenomenon could be observed elsewhere as well. Similarly, he thought that the problems identified in the report about the development of clinical governance were also common and were indicative of a leadership problem in the organisation.[176]

8.147 A question raised in the briefing paper in 2004 was whether all the points in the CHI report had been addressed. Many of these items individually, and all of them collectively, had serious implications for the safety of patients and the quality of service being provided to them. Yet it appears that some two years later, SaSSHA did not actually know whether these points had been dealt with. In fact, the Trust did not submit the required clinical governance development plan for 2003/04, although it appears that SaSSHA did have possession of the Trust's clinical governance development plan of May 2002, which the Trust had described as a "strategic response".[177]

8.148 Of the six points listed in the bullet points above, none were marked in this version of the plan as having been fully completed. The Trust action plan proposed, in relation to the staffing issue, to:

> *Develop an integrated workforce plan to support current and future service provision.*
>
> [Implement] [p]*olicy for redeployment of staff*[178]

8.149 A December 2002 version of the plan indicated some action on each of the six points, and one (awareness by staff of outcomes of complaints) was marked as complete.[179] With regard to the staffing issue, this version recorded that the action plan was complete, although it also stated that:

> *The A&E project will refocus elements of care delivery.*[180]

175 HCC0016000146, *Report of a Clinical Governance Review of Mid Staffordshire NHS Trust* (January 2002), CHI
176 Brereton T97.45–47
177 IRC/20 WS0000017151; IRC/21 WS0000017156
178 IRC/21 WS0000017164
179 IRC/21 WS0000017168
180 IRC/21 WS0000017174

8.150 The evidence before the first inquiry suggested that lack of feedback from complaints and incident reporting remained a constant cause for staff concern.[181]

8.151 The evidence, therefore, suggests that this was the state of knowledge, so far as SaSSHA was concerned, up to the point of the 2004 briefing paper.

Three-star rating in 2003

8.152 A CHI report published in July 2003 awarded the Trust a three-star rating, its highest level, signifying that it was one of the highest performers in the country.[182] The report referred to a review of the Trust's progress on its action plan following the 2002 governance review and merely commented that the Trust had "many strengths" without specifying what those were. The detail of the report showed that the Trust had achieved only one of its key targets, and had underachieved in two. While it was in the top band of trusts for clinical focus, it was in the lowest band for the emergency re-admission of children. However, it succeeded in being in the middle band for patient focus, and within that group it fell in the highest band for privacy and dignity.[183]

Children's service peer review in 2003

8.153 The conclusions of this review have been considered in *Chapter 1: Warning signs*. Any reassurance to be gained from the Trust's three-star status was somewhat countered by them. Serious causes for concern in A&E and on the children's ward were identified.

8.154 In the briefing prepared for the SaSSHA Board for the end of 2003/04 review of the Trust, Dr Myers listed conclusions of this review, including:

- An "immediate risk" in relation to the absence of triage for children arriving by their own transport;
- Only 50% of consultant and middle-grade staff in A&E and few nurses had paediatric life support training;
- Lack of a clear procedure for alerting staff of the imminent arrival of a critically ill child;
- Substandard equipment in the resuscitation area of the ward;
- Nurses nominated as responsible for the care of critically ill children were working beyond the reasonable responsibilities of their grades;
- Concerns were expressed by staff about feedback from critical incidents;
- Surgeons were caring for children without the involvement of paediatric medical staff: protocols for shared care were in place but they had not been agreed or implemented;

181 *Independent Inquiry into Care Provided by Mid Staffordshire NHS Foundation Trust, January 2005–March 2009: Volume 1. Chaired by Robert Francis QC* (February 2010), p 254, para 54 and pp 273–4, para 130
182 SHA0001000448, *Mid Staffordshire General Hospitals NHS Trust – NHS performance ratings: Trust detail report* (July 2003), CHI
183 SHA0001000450, *Mid Staffordshire General Hospitals NHS Trust – NHS performance ratings: Trust detail report* (July 2003), CHI

- Arrangements for emergency patients were heavily dependent on the goodwill of some anaesthetists and maintenance of paediatric skills among these staff was not being ensured;
- There did not seem to be an effective system for focusing on the needs of children.[184]

8.155 Important as the implications of these matters were for children, they would have affected all patients cared for by the Trust: for example, the deficiencies in feedback from critical incidents. There was an indication here of what became more apparent after the Royal College of Surgeons' (RCS) peer review in 2007, namely that the surgical division was dysfunctional. It was also open to question whether competent management would have allowed the state of affairs described in the children's services review to arise.

The Shropshire and Staffordshire Strategic Health Authority Board review of the Trust at the end of 2003/04

8.156 Dr Myers' briefing paper formed the basis of the SaSSHA Board's end of 2003/04 review of the Trust. This was a regular occasion on which the SaSSHA and Trust Executive teams met.[185] The paper contained the matters outlined above, excluding the staffing issues raised in the 2002 CHI report. There was a list of discussion points which included the question of whether all the CHI recommendations had been implemented and, if not, what the restraints were, and what progress had been made on the recommendations in the children's service peer review.[186]

8.157 The summary note of the board review meeting with the Trust only referred to these particular points under a heading of "Clinical Governance". Dr Myers was recorded as saying that:

> [B]*ased on previous evidence there was a fair degree of confidence that the structures and processes for Clinical Governance within the Trust were robust. She therefore drew attention to some of the specific issues raised by the peer review visit. She stated that it was important that the actions noted in the briefing sheet were taken forward. It was noted that the Trust had not submitted a Clinical Governance development plan for 2003/4.*[187]

8.158 Dr Myers explained to the Inquiry that this statement was intended to convey that there was a lack of complete confidence in the Trust's clinical governance processes.[188] The response

184 IRC/20 WS0000017152
185 Myers WS0000037070–1, para 51
186 IRC/20 WS0000017153
187 PM/4 WS0000037114
188 Myers T100.59

by Jan Harry, Director of Nursing at the Trust, of in effect declining to accept some of the concerns raised in the peer review, has been commented on in *Chapter 1: Warning signs*.

8.159 It was agreed that Dr Myers and Jan Harry would meet subsequently. They met on 4 August 2004 and discussed clinical governance issues. Unfortunately, no record of the meeting has been traced and Dr Myers cannot recall what the outcome was. The missing clinical governance annual report was eventually supplied to the SaSSHA.[189]

Comments and conclusions on Shropshire and Staffordshire Strategic Health Authority's performance management in 2004

8.160 The evidence shows that concerns were raised by external reviews, indicating the possibility of serious deficiencies affecting the safety of patients and the quality of care they received. These were known to SaSSHA, but there was no sense of urgency in ensuring that they had been addressed effectively.

8.161 Mr Brereton was challenged on whether a trust that could not evidence effective clinical governance could be regarded as properly managed:

> *THE CHAIRMAN: ... is that a symptom of a board that is not operating very well, or is it just a bit of executive inefficiency that a board might have overlooked?*
>
> *A. Those two points are related, of course, because executive inefficiency is something a board should deal with. And I always very much took the view that this was board business ... our feeling was that management and leadership at that trust at that time probably needed refreshing, and indeed we set about achieving refreshment in the year just after this report. And the reasons for that, if I'm blunt, were the reasons you, sir, raised, which was we had a feeling that this was a trust which probably didn't have sufficient edge in addressing the issues it was challenged with, and that that was increasingly becoming less acceptable as the expectations of NHS organisations rose. And throughout this period expectations of what NHS organisations would deliver and the way in which they would deliver them were rising, and quite properly so.*
>
> *THE CHAIRMAN: But if such an organisation, led or not led in the way you've described, has in effect no effective clinical governance, then how can you, at the SHA, be assured that every day of the week patients are being treated safely?*
>
> *A. You can't. And that's true. It is also the case that there were a number of other organisations in the same situation, which was why there was a general push on getting sound and secure clinical governance systems in place. It's true that these happened at different rates in different organisations ...*[190]

189 Myers WS0000037072–3, paras 58–60
190 Brereton T97.41–43

8.162 He went on to say that there had been a general assumption that the system was being "held together" by "the professional integrity of senior clinicians", and perhaps there had been an "over-reliance" on that assumption.[191]

8.163 The experience of Bristol showed beyond doubt that, in the absence of effective audit and other clinical governance measures, clinicians could not be relied on to ensure that patients were protected from poor care. Indeed, Mr Brereton went on in his evidence to point out that the problems of ineffective clinical governance were common and that, accordingly, the SHA had been seeking to systematise governance because the old reliance on clinical professionals had not been working. Therefore, it was not so much that there was a failure to recognise that there was a problem to be addressed, but a failure to recognise and address the potential and immediate implications it had for the welfare of patients currently being treated. This led to an unacceptable lack of urgency in requiring trust boards to remedy the governance deficiency and in seeking assurance that patients were in fact being properly cared for. Organisations that can demonstrate effective governance, which includes being able to show that their standard of provision is acceptable, may possibly be allowed greater latitude than those that cannot. For the latter category, it can be all too possible for poor care to go unheeded by those charged with ensuring that proper care is given, as is graphically shown by the experience of many patients at Stafford Hospital.

8.164 Dr Paulette Myers was asked why she thought it necessary to refer back to the 2002 CHI report in her briefing paper to the Board:

> *This would have been in 2002, before I started, and they would have been given time to put those actions into place. And it would have been as a consequence of not seeing all of those actions explicitly in place that we would then raise it formally at the end of year review ...*
>
> *To be fair to the SHA corporately, I don't know what was said in 2002 before I joined ... I can only reflect that ... at that point in time, myself and colleagues felt it needed challenging ...*[192]

8.165 Therefore, she had concerns that the Trust had not dealt with the points which had been raised before she assumed her clinical governance role, and quite properly wanted these followed up. It should have been a concern for all involved that deficiencies in clinical governance were, or might have been, outstanding for so long, but there is little to suggest that there was any sense of urgency on the part of the SaSSHA Board as a result.

8.166 The briefing paper did not refer to the concerns raised in the CHI report about staffing, even though this had been an area identified by CHI as requiring urgent action. At the time,

191 Brereton T97.43
192 Myers T100.56–57

workforce-related issues would not have been the responsibility of Dr Myers as Head of Clinical Governance, but of the Director of Workforce Development.[193] However, such division of responsibilities leaves open the risk that the quality implications of staffing are not fully considered and acted on.

8.167 The SaSSHA Board appears to have been satisfied at its review with the Trust by superficial assurances that progress was being made. No issues were raised about staffing, doubtless because their attention had not been drawn to this as a potential issue to be explored.

Loss of the three-star rating in 2004

8.168 In 2004, CHI re-rated the Trust. It went from a three-star trust to a zero-star trust. As is shown in *Chapter 1: Warning signs*, SaSSHA knew not only of the loss of rating, but also of the factors likely to have been behind this: failure to meet targets for elective surgery, outpatient waiting times, cancer waiting times and financial performance. SaSSHA attributed these failings to inadequate executive leadership at the Trust and a Minister was briefed to this effect by Philip Taylor in September 2004.[194] The Minister was assured that:

> *The SHA will* [following the preparation of a Trust Improvement plan and an assessment of the abilities of the executive team] *ensure delivery against the Improvement Plan and all national standards and targets.*[195]

8.169 A *Stars Recovery Plan* was produced by the Trust in November 2004.[196] This analysed the reasons for the change. The Trust had significantly underperformed in relation to two out of nine key targets (outpatient and elective waiting times) in three months of 2003. Thereafter, as stated in the *Stars Recovery Plan* an action plan resulted in those targets being met for the rest of the year. The Trust had also underachieved in two other targets (cancer two-week waiting times and financial balance). However, the Trust was said to have done well on the items in the "balanced scorecard", where it achieved an average or above-average score on all but five of the 36 items. The items where the Trust had underachieved were stroke care (it had no acute stroke unit, but one was planned), complaints (the complaints department was now being managed directly by the Chief Executive), consultant appraisal (it was suggested that the recording process was not complete) and the waiting-time issues referred to above.[197]

193 Myers T100.44; T100.68–70
194 SHA0002000188 *Follow-up to Minister of State for Health Meeting with David Kidney MP and Tony Wright MP (23 September 2004)*, Philip Taylor, SaSSHA
195 SHA0002000189 *Follow-up to Minister of State for Health Meeting with David Kidney MP and Tony Wright MP (23 September 2004)*, Philip Taylor, SaSSHA
196 SHA0002000001 *Stars Recovery Plan 2004–2005* (17 November 2004), Mid Staffordshire General Hospitals Trust
197 SHA0002000002–4 *Stars Recovery Plan 2004–2005* (17 November 2004) Mid Staffordshire General Hospitals Trust

8.170 The evidence suggests that SaSSHA officials were not particularly concerned at these developments.

8.171 Mr Taylor thought that the loss of stars was due mainly to poor record-keeping as a result of a new computer system, leading to a failure to meet targets, rather than anything of more serious concern.[198]

8.172 Mike Brereton, Chair of SaSSHA, attributed the loss of stars to the failure to meet waiting-time targets. He thought the star system was "crude" and "mechanistic", and observed that, although targets had not been met:

> *The balanced scorecard assessment indicated strong clinical performance at the Trust and adequate patient focus (i.e. middle band performance).*[199]

8.173 The Trust itself similarly did not believe that the loss of stars reflected any change in the quality of the service. Ms Morrey told the Inquiry:

> *... I believe this was due to the Trust not achieving waiting time targets. At the time the Trust put this down to a change in its IT system. It was not therefore perceived as a quality issue, but rather a consequence of administrative inefficiency.*[200]

8.174 It has to be said that if the analysis in the *Stars Recovery Plan* was correct then the deficiencies causing the loss of stars did not necessarily raise issues of patient safety or the quality of the service provided. Yet the SaSSHA, as with other organisations in the system, relied on the star ratings as an assurance that the quality of service was adequate. Indeed, it was intended to be the principal measure in that regard. Therefore, an inconsistent approach was being adopted. When the news from the rating system was positive, either by way of a good star rating, or good scores on the balanced score card, this was taken to be reassuring with regard to quality, whereas negative results were discounted. Therefore, there was an element of false assurance being taken and a lack of association of concerns about the competence of management with the potential and current effects on patients. In this instance, this led to the SaSSHA and the Trust to react symptomatically to the particular elements leading to the loss of the star rating rather than considering whether there was concern for patients arising out of the overall picture. Therefore, the focus of the Trust's *Stars Recovery Plan* and the SHA's management of it, was ensuring compliance with those targets for the then current year.[201]

198 Philip Taylor WS0005000428, para 13
199 Brereton WS0000037201, para 36
200 Morrey WS0000011200, para 10
201 PT/1 WS0005000446–52; Philip Taylor T71.135

Performance review December 2004

8.175 Following a mid-year review meeting in December 2004 to consider performance during 2004/05, Philip Taylor was able to send the Trust an encouraging letter:

> *The Trust's performance against key non-financial targets is looking good although some further improvements will be necessary to ensure delivery of these key areas. The exceptional progress made in emergency care is particularly impressive and the Trust is to be congratulated.*[202]

8.176 The summary of the meeting enclosed indicates that discussion was entirely around the current key performance indicators. The financial issues were also discussed separately from the non-financial indicators, and there is no record of any consideration of any possible linkage between the two.[203]

Foundation trust diagnostic exercise from 2005 to 2006

8.177 This is described and considered in *Chapter 1: Warning signs* and *Chapter 4: The foundation trust authorisation process*.

Children's service peer review in 2006

8.178 The 2006 review is fully described in *Chapter 1: Warning signs*.[204] This mechanism demonstrated its value by revealing a serious state of affairs at the Trust requiring immediate action.

8.179 Although organisationally separate from the peer review team, which was led by Jane Eminson, SaSSHA was made aware of the results of this review by being sent a copy of Ms Eminson's letter to the Trust of 18 January 2006, expressing concerns about the immediate risks.[205] However, the report was not seen at the time by Dr Myers. She had little doubt what her reaction would have been had she seen it:

> *If I'd seen this at the time, this would have been serious. And we would have certainly – involving Rob Willoughby as the children's lead – written to the trust ourselves ... So the same process would have been implemented, but with a very tight turnaround, probably a matter of a couple of weeks to get the responses, because they're down as "immediate".*[206]

202 Philip Taylor WS0005000440, para 62; PT/19 WS0005000606
203 PT/19 WS0005000607–11
204 The report itself can be found at CJE/10 WS0000023220
205 CJE/11 WS0000023245
206 Myers T100.80

8.180 She would have expected SaSSHA's reaction to have been one of "all hands to the pump". She could only speculate why this had not happened, but suggested it could have been because of the reorganisation then taking place and the fact that a number of people were changing their jobs.[207]

8.181 After the reorganisation Eamonn Kelly, Director of Commissioning and Performance, was briefed on the children's peer review programme as a whole in August 2006 and, at a follow-up meeting in November 2006, on trusts causing concern in this regard, including the Trust. He told Ms Eminson that he would follow matters up with Jonathan Lloyd and in performance discussions with relevant PCTs, but there is no evidence that he did so.[208] The reason for this is likely to have been that, at the time, the information about the Trust did not cause him the level of concern that Dr Myers told the Inquiry she would have felt if she had been shown the report.[209] Further, he did not actually read the report at the time. Having done so, he accepted that, in hindsight, and taken with other evidence now known, it raised concerns that should have been followed up.[210]

8.182 This is an instance of a failure to take action on a matter of concern, which cannot be explained away by any contemporaneous absence of a system to bring it to the attention of an organisation responsible for addressing it. Dr Myers, on receiving the earlier report, had at least reported the matter onwards. On this occasion, the official at the WMSHA, to whom knowledge of the 2006 report was imparted, did nothing. Ms Eminson lacked a clear understanding as to who had responsibility for following up the necessary actions as a result of the findings. If only at a strategic level, this was clearly a matter for an SHA to sort out. Not having done so, the WMSHA was guilty of a serious dereliction of duty in not taking urgent action on the contents and implications of this review. The effect of this failure was demonstrated by the fact that information about this review was not shared with the HCC following the risk summit that took place in February 2007. See *Chapter 9: Regulation: the Healthcare Commission* for more information.

Healthcare Commission review of children's services in 2006

8.183 The HCC review of children's services in August 2006 classed the Trust as "weak" and as not meeting minimum requirements.[211] This was known to the WMSHA, and, indeed, in April 2007 Elizabeth Buggins, Chair of WMSHA, raised the issue with Toni Brisby, Chair of the Trust, as part of her appraisal. Ms Buggins was successfully assured by Mrs Brisby that the criticisms in the report were largely attributable to data failings and that an action plan would address them.[212] Ms Buggins might have been less easily persuaded of this had she been aware of the recent

207 Myers T100.80–81
208 Kelly WS0000021725–6, paras 104–105; Eminson WS0000022929–30, paras 49 and 53
209 Kelly T75.113
210 Kelly T75.113–115
211 AG/6 WS0000024200
212 Buggins WS0000022533, para 59; EMB/5 WS0000022630

West Midlands peer review into children's services. As her evidence recited in *Chapter 1: Warning signs* makes clear, had the full information been available to the SHA, she believes that different judgements might have been made.[213]

Interaction with the Trust on finance

8.184 Descriptions of the financial climate in the NHS during the period under review, and the Trust's efforts to bring its finances into line, are to be found in *Chapter 2: The Trust*. It was concluded in each that, while the Trust Board had to take responsibility for the results of the cost-cutting measures it took, it had been, like all trusts, subject to relentless and continuous pressure to balance the books, without any equal pressure to take into account the effects on the standards of the service provided.

8.185 The SHA played its full part in exerting this pressure.

Shropshire and Staffordshire Strategic Health Authority

8.186 In May 2005, Dr Bernard Crump, Chair of SaSSHA, met the Trust Board for an end of year review of performance in 2004/05.[214] He noted the Trust's achievements in meeting the A&E, inpatient and cancer waiting-time targets, but expressed concern about financial performance.[215] At the meeting, SaSSHA asked whether the carrying of vacancies, some of which were filled by bank staff, caused difficulties in delivering consistent patient services. The Trust's response was recorded as:

> *The Trust continued to monitor the situation to ensure that service quality was maintained.*[216]

8.187 It was agreed that the workforce profiles would be discussed again at the mid-year review.

8.188 In the discussion on the Trust's financial position, SaSSHA was recorded as expressing "serious concern".[217] In a letter enclosing a summary of the meeting, sent on 27 July 2005, Dr Crump said:

> *... it is very important that you address this as a matter of very great urgency. The Financial Recovery plan will place great demands on the Trust during the coming year and we are confident that you and your team understand the importance of this.*[218]

213 Buggins T74.86
214 Philip Taylor WS0005000440, para 64
215 PT/21 WS0005000619
216 PT/21 WS0005000620
217 PT/21 WS0005000622
218 PT/21 WS0005000619

8.189 In October 2005, in a letter to trusts, Antony Sumara, Managing Director of SaSSHA, stressed the difficult financial position across the West Midlands and listed ten measures "that need to be taken" in order for trusts to meet their financial responsibilities. It was said that the measures were "not about compromising clinical services", but about improving productivity and clinical care to patients. They included headcount reduction plans and a forensic review of each trust's business position. The measures were "all about the short term necessity of reducing deficits".[219]

8.190 At a meeting between Martin Yeates and David Nicholson in the same month, as reported to the Trust's Financial Performance Committee,

> *... it was made very clear that he* [David Nicholson] *was expecting a break even, there was a strong message for the Trust to resolve the situation.*[220]

8.191 John Newsham, Director of Finance at the Trust, was clear in his evidence that correcting the deficit was a matter for which the Trust leadership could be held to account:

> *THE CHAIRMAN: – a third year of deficit would be something for which the senior management would be held to account?*
>
> *A. Yes.*
>
> *THE CHAIRMAN: And the reasons that you've given us today in relation to the history of that deficit would not be accepted as reasons justifying it?*
>
> *A. No. I think in that financial year as well the regional health authority in total was in difficulty, and we were a component part of that. So it was essential that each organisation's financial position improved in ... order that the regional health authority position improved and broke even at the end of the year.*[221]

8.192 While exerting this pressure, SaSSHA did express an interest in the effect of savings on services, as evidenced by the May 2005 meeting between the Trust Board and Dr Crump, and did make it clear that it expected the deficit correction to be achieved without a compromise in services, as expressed in Mr Sumara's letter. In practice, however, little occurred to marry up any assessment of the proposals for savings with the impact on services. Philip Taylor was asked about this in the context of the May 2005 meeting:

> *Q ... That seems to suggest that the SHA was dependent on the Trust's assurances that its workforce policy could be conducted without an impact on service quality.*

219 AS/4 WS0000005959–61; DN/13 WS0000068083
220 JN/8 WS0000012094
221 Newsham T60.103

A. Yes, and I think on the whole we were, yes. We were reliant on their assurances that it could be done and on their planning to do it and on their execution of those plans.[222]

8.193 Asked whether SaSSHA saw a risk assessment, Philip Taylor said:

I think the risk assessment was the responsibility of the NHS trust. The SHA's responsibility would be to make sure that risk assessment was being carried out by the trust not do the risk assessment itself.[223]

THE CHAIRMAN: Would you want to – not you personally, but would you the SHA want to see the risk assessment?

A. We would generally want to know that it was being done, but I don't recall us asking for them to be sent to us.[224]

8.194 Indeed, the effect of the Trust succeeding in balancing its books, and even producing a surplus, was that there was less scrutiny. For example, Mr Taylor stopped meeting the Trust's Director of Finance on a fortnightly basis as a result.[225]

8.195 The Trust's financial recovery plan for 2004/05 to 2008/09 was produced in the context of the demands from the centre that all trusts in deficit break even (see above).[226] The plan proposed a reduction in staffing of 180 whole time equivalent (WTE) posts between January and September 2005.[227]

8.196 The Trust's CIP for 2006/07 included totalling about £10 million, which represented approximately 8% of the Trust's turnover. The programme included a headcount reduction of about 150 WTE posts. This amounted to about 5% of the Trust staff.[228] Philip Taylor did not consider it part of his role to question the potential impact of these measures:

If my colleagues in the Workforce and Clinical Governance Directorates had had any concerns about whether this was achievable without affecting patient care, no doubt these would have been addressed with the Trust before the plan was approved.[229]

8.197 Philip Taylor confirmed in his oral evidence that the Trust's financial recovery plan for 2004/05 to 2008/09 would have had to be "signed off" by both these directorates.[230] He also regarded

222 Philip Taylor T71.183
223 Philip Taylor T71.184
224 Philip Taylor T71.192
225 Philip Taylor T71.192
226 JN/3 WS0000011987
227 JN/3 WS0000011995; PT/5 WS0005000480; Philip Taylor T71.171–172
228 Philip Taylor WS0005000435, paras 44–5; PT/14 WS0005000589
229 Philip Taylor WS0005000435, para 45
230 Philip Taylor T71.181

the percentage savings planned in the Trust's CIP for 2006/07 as comparatively high but not out of line with what was being proposed by some other trusts.[231] That the SHA would not have considered this sort of programme exceptional is illustrated by the evidence of Peter Blythin (who had not been in the SHA at the time these plans were proposed). He said that, at the time he first met Dr Helen Moss after her appointment as Director of Nursing at the Trust, he would not have known about the size of the CIP for the previous year.[232] He therefore would have had little context when she later sought advice from him on conducting a review of staffing and skill mix. However, by this time, the SHA merger had taken place and the resources available to scrutinise quality at trusts had been reduced further, resulting in the WMSHA taking a more distant role.

Handover to West Midlands Strategic Health Authority

8.198 The existence of the Trust's £10 million CIP for 2006/07 was made known to the WMSHA during and following the transition.

8.199 On 31 May 2006, and again on 21 July 2006, Martin Yeates wrote to Peter Spilsbury, the member of the SHA transition team with responsibility for planning the local delivery plan process during the transition and then the WMSHA Director of Strategy, asking for a £1 million loan to support redundancy costs arising out of the CIP.[233] The correspondence included details of the plan and a breakdown of the workforce reduction numbers. Mr Yeates offered assurance that this was being effected without prejudicing clinical standards:

> *I have also outlined the Medical Division proposals as this indicates the skill mix changes rather than a straight headcount. It is important that it is recognised that our fundamental review has not just been in relation to headcount but a reduction of cost and mindful of the need to deliver good standards of clinical care.*[234]

8.200 In September 2006, Philip Taylor sent Peter Shanahan (who had begun to take on some of his responsibilities as the newly appointed Director of Finance and Capacity at the WMSHA) a letter including handover details of all organisations for which SaSSHA had been responsible. Understandably, the letter focused on organisations which had been causing SaSSHA concern, including two NHS trusts which were in financial turnaround. With regard to the Trust, in a five-line reference Mr Taylor stated that it had performed "well" in 2005/06 and was planning a surplus of £1 million in the current year (2006/07).[235] No mention was made of the £10 million CIP because, Mr Taylor explained, he had been assured the Trust was "delivering financially".[236]

231 Philip Taylor WS0005000435–6, para 47
232 Blythin T69.118–20; Blythin WS0000019654, para 64
233 Spilsbury WS0000057187–8, para 34; PWS/4 WS0000057232
234 PWS/4 WS0000057238
235 Shanahan WS0000020506, paras 38–39; PWS/3 WS0000020721
236 Philip Taylor T72.30–31

8.201 Mr Shanahan told the Inquiry his approach would have been different, had such a CIP been planned during his tenure:

> *Had a £10 million CIP been planned during my time in office, it would have been flagged by my team as a potential issue … I cannot comment on what process the former SHAs took to validate the reasonableness of those plans, as I was not involved in that process. The WMSHA would have been responsible for monitoring the 2006/07 plan, but we would not have reviewed the plan itself, unless there was some flag to indicate it might be problematic.*[237]

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8.202 With regard to financial oversight, the WMSHA's attention was focused on organisations other than the Trust, principally those to which attention had been drawn in the handover letter. Given the lack of linkage made by the WMSHA between CIPs and quality of care, no need was perceived for scrutiny of the Trust's CIP, particularly as it appears to have been substantially completed by November 2006, at about the time Mr Shanahan took up his post substantively as Director of Finance and Capacity at the WMSHA. As a small finance team, required to oversee the finances of 40 organisations, they were simply not interested in how a trust achieved its CIP, merely that it did so:

> *In 2007/08, we would not have looked at whether the Trust was delivering a plan in the way that it said it would, rather we were interested in whether the plan, as a whole, was delivered …*
>
> *If any concerns had arisen as a consequence of the Trust's financial planning with regard to the quality of care for patients, I would have informed the Director of Nursing and Workforce at the SHA, who would then have taken "ownership" of the issue.*[238]

8.203 Reliance was placed on the boards of trusts to manage performance and to hold the executive to account for how a CIP was implemented. In the absence of any systematic liaison between the finance team and the clinical officers of the WMSHA, it is difficult to envisage circumstances in which the WMSHA's finance team could have been caused to refer a concern in the way described by Mr Shanahan. He certainly could not recollect ever having done so himself.[239]

237 Shanahan WS0000020507, para 44
238 Shanahan WS0000020508–09, paras 50–51
239 Shanahan WS0000020509, para 51

West Midlands Strategic Health Authority risk assessment of the Trust – 2007

8.204 Steve Allen told the Inquiry that, in July 2007, the WMSHA undertook a risk assessment in accordance with the principles set out in the West Midlands performance management framework for all organisations in the region.[240] As this was before the framework was formally published, and before Mr Allen was appointed, he thought this was, in effect, a test of the concept, and a "dry run".[241] It may not have been circulated. The Trust was rated as "red" for quality and safety because of three issues:

- It was not meeting the HCAI target, in particular for MRSA, and had no plans to reduce this;
- It was not fully compliant with the Hygiene Code;
- It had a high mortality rate (see *Chapter 5: Mortality statistics*).[242]

8.205 For governance, the Trust was rated "amber" overall but given a "green" or "low" rating by the SHA. The document did not specify any reasons for this rating.[243]

8.206 Mr Allen made it clear to the Inquiry that these ratings did not distinguish it from other trusts in the region. Several were not meeting their HCAI targets, six others were not compliant with the Hygiene Code and four others had comparably high HSMRs.[244] Further, there were FTs, not in this list as they were not performance managed by the WMSHA, who had comparable concerns in relation to HCAIs.[245] At the time, when it came to HCAIs, the WMSHA was the worst performing SHA in the country.[246]

8.207 The Trust was only assessed on this one occasion against this framework, as it became an FT in February 2008 and was therefore no longer covered by the WMSHA risk assessments.[247]

8.208 This bleak assessment of the Trust does not seem to have led to any intervention on the part of the WMSHA apart from the work on mortality considered in *Chapter 5: Mortality statistics* and the actions summarised below.

240 Allen WS0005000166, paras 54–57; STA/8 WS0005000274
241 Allen T71.52–53
242 Allen WS0005000167, para 61
243 STA/8 WS0005000282
244 Allen WS0005000167, para 61
245 Allen T71.56–57
246 Allen T71.59
247 Allen WS0005000168, para 63

Non-financial performance management of the Trust

8.209 Steven Allen had a number of handover meetings with Jonathan Lloyd, which covered the latter's assessment of matters to watch. The Trust was not one of them.[248] No concerns were raised about the Trust at the monthly WMSHA Patient Safety Forum meetings.[249]

8.210 Following the HCC report in October 2007 on the outbreaks of *C. difficile* at Maidstone and Tunbridge Wells, the Health Protection Agency (HPA) published comparative data on rates at different hospitals. The Trust had a rate of 3.66 cases per thousand bed days for the first six months of 2007; less than the previous year, and average for the WMSHA at the time.[250] The WMSHA produced an action plan for the region on infection control in November 2007, which received emphatic endorsement from Cynthia Bower in a presentation.[251] The presentation showed that HCAI was a matter of serious concern for the WMSHA:

- *C. difficile* numbers had risen faster in the region than nationally;
- Recent improvements masked a long-term trend;
- The region had the worst performance in England for MRSA and the overall numbers of cases were rising. [252]

8.211 Ms Bower required a "sustained push on this until we have cracked it". Among the messages in the presentation were:

> *I cannot and will not accept the easy argument that you can either hit targets or have safe treatment but not both. Mature organisations manage both ...*
>
> *Your Boards MUST:*
>
> *...*
>
> *Ensure adequate governance arrangement are in place and take reports;*
>
> *Ensure that the messages (e.g. Root Cause Analyses) are being acted upon ...*
>
> [Trust directors] *must have personal assurance that what you say in the Board is happening on the Ward. You need to get about and see with your own eyes (PCTs too!)...*[253]
>
> *...*
>
> *Don't get distracted by data issues.*[254]

248 Allen WS0005000168, para 67
249 Allen WS0005000168–9, para 68
250 Allen WS0005000169, para 70
251 STA/10 WS0005000288
252 STA/10 WS0005000291 and WS0005000296
253 STA/10 WS0005000288 and WS0005000292
254 STA/10 WS0005000292

8.212 The action plan included the risk-based support and inspections by the SHA with PCTs, deep cleaning funded by the WMSHA and an education programme.[255] The Trust would also have been included in a programme of visits and calls from the HCAI team.[256]

8.213 The WMSHA approach to this issue (which appears to have been effective in reducing the HCAI rate),[257] is in marked contrast to that taken over high mortality rates (see *Chapter 5: Mortality statistics*). However, although there was a focus on direct support and monitoring of the infection issue, it did not result in general concerns about the Trust coming to light.

8.214 The Trust will also have received attention from the WMSHA in relation to its poor performance against the A&E target. As shown in *Chapter 2: The Trust* and *Chapter 23: Nursing*, it is clear that considerable attention was paid at the Trust to correcting this, to the extent of unacceptable pressure being imposed on staff. According to Mr Allen, the WMSHA contribution was that it:

> *... engaged with Local Health Economies (including South Staffordshire) to ensure escalation plans were being put in place on days when the emergency care system was under pressure.*[258]

8.215 These measures did not detect the significance of the short staffing of the Trust's A&E or the other issues, apparent in the 2006 peer review of children's services.

West Midlands Strategic Health Authority interaction with the Trust on nursing skill mix

Conclusion of the first inquiry

8.216 The first inquiry examined the actions of Dr Helen Moss, Director of Nursing at the Trust, in relation to the nursing staff skill mix at the Trust. It was concluded that shortly after her arrival in December 2006 she became aware of concerns about this issue, and set up a skill mix review. She, and the Trust, were criticised for the time taken to undertake the review and implement its conclusions. Taken with the staff reductions, which had led to the staffing deficiencies, it was observed that:

255 STA/10 WS0005000299
256 STA/10 WS0005000296
257 Figures for MRSA and *C. difficile* exhibited some improvement in 2008–09, and clear improvement in 2009–10 www.midstaffs.nhs.uk/About-Us/Statistics/Infection-Rates.aspx
258 Allen WS0005000170–71, para 75

... the [Trust] *Board neither received nor sought sufficient professional advice about the impact of the changes it was approving in terms of the workforce reduction, and then when it was told that there were or could be staff deficiencies, failed to follow up those concerns with any urgency ...*[259]

8.217 This Inquiry has looked at the awareness of the WMSHA of the staff deficiency and its involvement in the skill mix review.

The role of the Director of Nursing and workforce

8.218 Mr Blythin assumed this post at the WMSHA in October 2006. Part of his responsibilities was to assess the workforce plans of all NHS organisations in the region.[260] As Director of Nursing, he acted as a mentor and, where requested, adviser for trust directors of nursing in the region. It was not, according to Ms Bower, a WMSHA responsibility:

... to ensure that there was a safe level of staff to deliver an acceptable quality of care – this was the responsibility of the organisation itself.[261]

8.219 Nonetheless, Mr Blythin was in a position to offer advice and assistance to Dr Moss and did so.

Initial knowledge of nursing staff deficiencies

8.220 At the outset, there were few facts known to Mr Blythin from which he might have been expected to realise there was a deficiency in the Trust's staff. The financial monitoring returns on the Trust and other material, some of which has been considered above, would have been available to the WMSHA as a whole, and this included reference to the CIP and the workforce reductions. However, no issue was referred to him in this regard, and, even if the information had been perused by him, it is unlikely that he would have interpreted it as a cause for concern.[262] He was unaware of:

- The 2002 CHI governance review and its concerns about nurse staffing;
- The 2003 children's services peer review;
- The 2005 Barry report;
- The 2006 children's services peer review.

259 *Independent Inquiry into Care Provided by Mid Staffordshire NHS Foundation Trust January 2005–March 2009, Volume One* (24 February 2010), p 238
260 Blythin WS0000019639, para 15
261 Bower WS0000020988, para 45
262 Blythin WS0000019654, paras 64–65

8.221 Mr Blythin told the Inquiry that there was nothing presented to the WMSHA Board in 2006/07 to suggest there was a problem at the Trust. Today, the WMSHA has more sophisticated systems in place to show, for example, the nurse to bed ratio and other measures of staffing adequacy.[263]

Involvement with skill mix review

8.222 Mr Blythin first met Dr Moss at her request in March 2007 for an induction meeting. There was nothing unusual about this type of meeting with a newly appointed nursing director. Mr Blythin recollected that she had told him her working environment at the Trust was different from what she had been used to at her previous trust. She had less professional support and had to give greater personal attention to the detailed implementation of her work as a result. He gave her advice on this. She raised no concerns with him at that time.[264]

8.223 In fact, Dr Moss had begun, within the first few months of her arrival, to harbour concerns about the workforce at the Trust. In addition to seeing that the "basics of good nursing were not being done", she realised that the numbers and skill mix of nurses "was not right", but she did not, at least initially, appreciate the scale of staff reductions that had preceded her arrival.[265] In part, this was caused by difficulties in establishing what the actual numbers were. This may well explain why she did not raise such concerns with Mr Blythin at their first meeting.

8.224 Dr Moss first raised her concerns about the nursing staff numbers and skill mix at a meeting with Mr Blythin some time between July and September 2007.[266] His recollection was that:

> *She was convinced that she didn't have enough staff, but one of the issues that she had to demonstrate was the evidence to the board and she made it clear that she didn't have enough staff when we spoke in September. But I think – you know, I'm very clear that that was – she was making evident to me that she did not have enough staff in the September.*[267]

8.225 Mr Blythin accepted that this was potentially a matter of serious concern for patients:

> *Q. I mean, you would have appreciated, as a registered nurse yourself, that not having enough nursing staff means real things for real patients?*
>
> *A. Absolutely.*[268]

263 Blythin WS0000019655, para 70
264 Blythin WS0000019657, para 74
265 Helen Moss WS0000009459–62, paras 22–27; T62.9–18
266 Blythin T69.125–127
267 Blythin T69.127–128
268 Blythin T69.128

8.226 He was also clear that at the same time he would have asked Dr Moss whether she had appropriate arrangements in place to cover shortages with agency and bank staff.[269] He assisted Dr Moss in initiating a skill mix review by approaching an experienced nurse to undertake it.

8.227 Mr Blythin and Dr Moss remained in regular contact during the review, and neither she, nor the nurse reviewer, raised any concerns with him about the standards of care being provided.[270]

8.228 In February 2008, Ms Morrey, Chief Operating Officer at the Trust, contacted Mr Blythin to discuss difficulties in meeting the A&E waiting-time target, and to express concern about medical staff levels. Mr Blythin put her in touch with the University Hospital of North Staffordshire for assistance in this regard.[271]

8.229 On 27 February 2008, Mr Blythin visited the Trust with Ms Sawbridge of SSPCT to discuss nurse staffing and, in particular, the review that Dr Moss was intending to present to the Trust Board. He visited A&E and Wards 10 and 11 to talk to staff about the review and to find out how they were feeling about it.[272] The review had identified a need for 120 additional WTE posts, which would require funding in the order of £3 million a year.[273] He met Martin Yeates who expressed his support for the review.[274] Mr Blythin's visit happened to coincide with an unannounced inspection of A&E by the HCC. He attempted unsuccessfully to speak to Dr Heather Wood, who was leading the inspection.[275]

8.230 Because of the size of the nursing deficit that had been identified, Mr Blythin stayed closely in touch with Dr Moss. However, the review was not ready to be presented to the Board until March 2008, over a year after Dr Moss first appreciated there were insufficient staff numbers.

Subsequent involvement in staffing issues

8.231 In April 2008, Mr Blythin received a copy of a report by Ms Sawbridge of an unannounced visit conducted by SSPCT to the Trust's A&E, the EAU, and Wards 7, 8, 11 and 12. This visit followed the HCC's announcement of its investigation following its own unannounced visit, and the receipt by the SSPCT of concerns from GPs and serious complaints from members of the public. The summary of the visit stated that:

269 Blythin T69.128
270 Blythin WS0000019670, paras 121–122
271 Blythin WS0000019671, para 124
272 Blythin WS0000019671, para 125
273 PB/22 WS0000019953
274 Blythin WS0000019673, para 131
275 Blythin WS0000019672, paras 126–127

Although there were undeniable areas of concern, and staff shortages were a reality on some wards, many patients were positive about their care, and the inspection team noted a largely clean environment with new equipment and some good examples of care. This visit identified some urgent areas for improvement, and an action plan has been developed with the Trust to address the staffing shortages and clinical leadership issues in the short term.[276]

8.232 In the report itself, the summary conclusion strained to balance the negative with the positive:

In summary the overall conclusion was that staffing levels needed improving, but that most patients were not receiving poor care as a matter of routine. There were clearly issues that needed addressing to ensure that all patients received good standards of nursing care, but some positive stories were heard, and the environment was largely clean and equipment was new.[277]

8.233 The matters of concern recorded in the report included the following:

- EAU:
 - An elderly patient had not been offered food or drink or pain relief since admission. While he may have been designated "nil by mouth", he was unaware of this and did not know what was to happen next;
 - Another patient had been waiting for discharge and tablets for five hours;
 - A further patient described seeing a cleaner using the same cloth on a toilet and a sink;
- A&E:
 - There was no triage because there were two seriously ill babies in resuscitation;
 - Staffing levels were below establishment;
 - Several patients with less serious conditions had been waiting "considerable lengths of time" with no information about what to expect;
 - Patients were not eating or drinking because of being unsure whether it was safe for them to do so;
 - A man with steel in his eye and a child with a minor head injury who had been in A&E "for many hours" had not been offered pain relief;
 - Zimmer frames were stacked in a toilet;
 - A sluice had corroded pipes and tiles needed cleaning;
 - There was no record of when toilets had last been cleaned;
 - Privacy and dignity were compromised by curtains not being pulled round cubicles;
- Wards 11 and 12:

276 PB/27 WS0000019982–3
277 PB/27 WS0000019986 SHA0011000150

- Staff were very demoralised and short staffed. The establishment was four registered and four non-registered but there were only three of each on duty for 20 beds;
- There was only one sister to cover three ward areas;
- A high staff sickness rate was reported;
- A female patient had been left in a soiled nightdress since lunchtime. Relatives had been refused permission to clean her for purported "health and safety" reasons. She had not been changed by evening visiting time;
- Poor communication was reported by one family.[278]

8.234 In contrast, little was found worthy of negative comment in Wards 7 and 8.[279]

8.235 The report noted that £1.15 million had been agreed to pay for additional nurses and that a recruitment campaign had delivered 70 nurses who would start in May. However:

> *Establishment review identified the need for over 120 nurses in order to staff the wards at the required level for quality of care, so there remains a significant gap even when this recruitment drive is completed. This would require an additional investment of £1.5 million, and this has not yet been agreed by the Board.*[280]

8.236 The report contained no reference to any timetable for filling this gap in what was required to ensure a proper quality of care.

8.237 The report's summary again sought to balance the negative by emphasis on the positive:

> *Clearly wards 11 & 12 and A&E were the areas needing most support, but the situation was not considered unsafe and A&E clinical care was appropriately prioritised.*[281]

8.238 However, a series of actions was recommended or in place, which included further unannounced visits on a fortnightly basis.[282]

8.239 Mr Blythin met Dr Moss and Ms Sawbridge to discuss the report on 28 April. In a follow-up email on the following day, he expressed his appreciation of what was being done. He found "encouraging" the fact that "plaudits about nursing care had risen" and was "pleased to see that the PCT and the Trust have undertaken to maintain formal contact" about nurse staffing levels, recruitment and patient feedback. He approved of the fact that care standards and patient environments were to be reviewed by Ms Sawbridge from a commissioning

278 PB/27 WS0000019995–6
279 PB/27 WS0000019996
280 PB/27 WS0000019997
281 PB/27 WS0000019996
282 PB/27 WS0000019997–98

perspective and that joint "walkabouts" had been carried out. He indicated a wish to meet again shortly, in a few weeks time.[283]

8.240 The conclusions in the report were arguably more positive than the findings warranted, but it should have left no doubt over the gravity of the effect of the staffing shortage and at least the potential risk to patients. Although he did follow up the report in a meeting with Dr Moss and Ms Sawbridge, Mr Blythin's reaction to this report did not reflect the seriousness of the situation. He told the Inquiry :

> *The report to the PCT Board did highlight undeniable areas of concern, but to a certain degree, and although not excusable, you could find issues of this type at other Trusts. Hospitals are very complex, and there are risks attached to providing healthcare. Despite well documented procedures and good practice, occasionally, for example, patients will be given the wrong medication or accidentally fall out of bed. The issues identified by the PCT would not have caused me to take direct intervention because of the direct action of the PCT. If anything, I was reassured by the level of monitoring which the PCT had in place.*[284]

8.241 This reaction is concerning. It came against a background, within his own knowledge, of a high HSMR, an HCC investigation, and the disclosure of a number of complaints from members of the public. Whether or not safe care was actually being delivered at the time of the visit, there were clear reports of unacceptable standards of care in more than one area, and understaffing, the full remedy for which was not even being planned. It was and should have been clear that patients were at risk and that urgent action was needed. When considered from the patients' perspective, to suggest that such conditions might exist elsewhere merely heightens the concern, rather than excuses the findings. Regrettably, even taking account of the limitations on the actions an SHA could take with regard to an FT, Mr Blythin's reaction speaks of a willingness to tolerate a service being offered that was in truth unacceptable, and which even he himself described as "not excusable". It would, however, be unfair to single out Mr Blythin because he was far from being alone in taking such a supine attitude. The PCT report to the Board, as has been noted, sought to place as positive a gloss as was possible on their appalling findings. Unfortunately, Mr Blythin's reaction was merely an illustration of a culture of tolerance of the unacceptable that pervaded the NHS system.

West Midlands Strategic Health Authority and the Healthcare Commission investigation of the Trust

8.242 As described in *Chapter 5: Mortality statistics*, the WMSHA had not been kept informed of the HCC mortality alerts sent to the Trust. The first that the SHA heard of the HCC's concerns about the Trust was on 14 January 2008, when Ms Nicola Hepworth of the HCC contacted Dr Shukla

283 PB/28 WS0000020065
284 Blythin WS0000019677, para 148

to tell her that the HCC had noted that the Trust had continually been identified in Dr Foster alerts. Dr Shukla requested that the HCC involve them given the work they were doing on HSMRs. She also asked Mr Steve Wyatt, of the WMSHA, to inform, confidentially, Dr Mohammed, who with Professor Lilford at Birmingham University was undertaking the commissioned research on mortality for the WMSHA.[285]

8.243 On 28 January 2008, the HCC emailed to the WMSHA a copy of Dr Wood's letter to the Trust referring to its concerns at the Dr Foster alerts, and its own diagnosis-specific mortality analyses.[286] It was clear from the letter that the HCC was considering whether to launch a formal investigation. An investigation was rare (only 16 were ever carried out by the HCC) and occurred only when prompted by strong evidence of serious concerns over patient safety, such as those that resulted in the report on Maidstone and Tunbridge Wells NHS Trust.[287]

8.244 At this point in time, the Trust was on the verge of being considered by Monitor's Board for authorisation as an FT.

8.245 The investigation team at the HCC were unaware of the Trust's status as an applicant for FT status, and it occurred to no one at the WMSHA who became aware of Dr Wood's letter that they ought to inform Monitor of this development.[288] Ms Bower explained that they assumed that Monitor and the HCC would be in touch with each other.[289]

8.246 On 29 January 2008, Dr Shukla passed on the HCC communication to Ms Bower. Her email referred to the coding issue, but added the caveat:

> *As for all our high mortality trusts the issue of coding has been a significant factor. However we cannot explain the high rates to be solely due to coding inaccuracies so we are auditing care for 3 specific conditions to examine as a proxy the quality of care provided by the trusts.*
>
> *This area is a potential minefield as Steve will attest. Depending on what subanalysis is done, there is bound to be a least one or more statistically significant abnormal results.*[290]

8.247 Dr Shukla proposed to have the matter discussed at the next research steering group meeting.

8.248 The potential urgency of the situation appears to have escaped the leadership of the WMSHA. They had been aware since April 2007 of the high HSMR at the Trust and other providers in their region. While coding quality was, clearly, one part of the problem, Dr Shukla was

285 Shukla WS0000018560, para 106; RS/37 WS0000019031
286 RS/39 WS0000019040–45
287 Ellis WS0000027756, para 30; Kennedy WS0000025868, para 120
288 Wood WS0000025052, para 104; Bower T73.128
289 Bower T73.128
290 RS/39 WS0000019040

accepting that it could not be the sole explanation. Yet by the end of January 2008, nine months later, even the limited planned review of the quality of care had not been undertaken. In any event, only two care pathways for specific conditions were looked at.[291] The SHA was no closer to answering the most important question for patients: was there high mortality due to poor care?

8.249 In her oral evidence and speaking with the benefit of hindsight, Ms Bower accepted there had been a mistake:

> *I wished that we had put together some things in different ways. I absolutely wished that the HSMR work had included an inspection and included a user voice, and I think that was the biggest single failing that we – the biggest single mistake that we made – a mistake that I wish I hadn't made. Because I believe if we had done that, we would have uncovered things. My only mitigation is that those actions would have been highly unusual for an SHA at the time.*[292]

8.250 The intervention of the HCC did not prompt a more urgent reaction. The focus of the WMSHA still appears to have been on considering a response to the HCC rather than exercising its own responsibility for the safety and quality of care. In spite of the background described, no attempt was made to alert Monitor to this development although it was still considering the Trust's application for FT status.

8.251 On 30 January 2008, Mr Allen replied to Dr Shukla's email:

> *I entirely agree with Rashmi* [Shukla]. *I think we should do everything we can to support Martin* [Yeates] *in responding. I also think as an SHA we should write separately to HCC to ask them to justify this approach to generating "alerts" given the high "false positive" rates which will arise.*[293]

8.252 Mr Allen explained that he was concerned at the significance being attributed to Dr Foster alerts by the HCC.[294]

291 Shukla WS0000018561, para 111
292 Bower T74.17
293 STA/12 WS0005000306
294 Allen WS0005000172, para 82

8.253 Ms Bower was surprised at the turn of events:

> *In February 2008, I was surprised that matters had got to the point where the HCC initiated an investigation and viewed the Trust so negatively without the WMSHA being made aware of their concerns. Whilst matters progressed rapidly from late summer/ autumn 2007 to early January 2008, in the 10 months since the Dr Foster HSMRs were published the WMSHA had gone through the process of challenging the trusts, carrying out death audits and clinical audits and commissioning a detailed report. I thought this was a robust response, which had involved us looking in detail at the organisations.*[295]

8.254 She told the Inquiry that at that stage she may not have understood the significance of the HCC having carried out work on its own alerts.[296] She also pointed out that the HCC itself was hesitant to ascribe too much significance to the alerts and was undertaking an exploratory exercise at the time.[297]

8.255 Even without the benefit of hindsight, this was a reaction of staggering complacency, based on an inaccurate analysis of what had happened to date. The SHA's response to the HSMR is considered in depth in *Chapter 5: Mortality statistics*, but it consisted of a focus on the coding issue, the report on which was not to emerge until June 2008, the acceptance of assurances from trusts as to clinical quality, and a review of three diagnostic groups that had yet to be completed. The WMSHA therefore continued to concentrate on defending the Trust by reference to the coding issue, rather than becoming immediately concerned about the potential implications for patient safety.

8.256 The WMSHA points out in its closing submissions, correctly, that the discovery of serious systemic failings in a recently authorised FT was unprecedented and that therefore it and other organisations were in new and unknown territory in relation to handling such an event. It claims credit for not washing its hands of the matter and for continuing to be involved, but points out that it had to be sensitive to the regulatory and oversight responsibilities of Monitor. Any criticism made of the WMSHA and its officers has been made with this point firmly in mind. It is unlikely that the change in status of the Trust affected the judgements those at the SHA made about the significance of the HSMR, the merit of the HCC decision to investigate the Trust, or its reaction to the HCC findings as they emerged. In any event, it had a continuing responsibility to ensure that the services commissioned from the Trust were being delivered – and had been delivered – in accordance with the required standards. If it could not, strictly speaking, intervene directly any more, it could do so indirectly via the PCT as commissioner.

295 Bower WSWS0000021016–017, para 139
296 Bower T73.129
297 Bower T73.164–165

8.257 On 27 February 2008, Mr Blythin visited the Trust to discuss the nurse staffing issue (see above). He visited clinical areas but saw nothing to concern him. It appears he was unaware at this time that the Trust had been authorised as an FT. In an email reporting his visit sent to colleagues on 16 March, he was asking for a discussion about the application process because he "had been unable to establish the timeline".[298]

8.258 On 28 February, Dr Shukla received further information from Dr Wood by telephone, following an unannounced visit to the Trust that day. Dr Wood explained the background to their concerns, including those relating to mortality.[299] While the HCC appears to have accepted that coding problems explained some of the alerts, it was concerned at the Trust's failure to supply information. By this time, it had also received a number of unsolicited complaints from a number of patients and relatives concerning the standard of care. The visit, Dr Wood reported, had disclosed cause for concern:

> *There were concerns about nursing that related to numbers of nurses available at night, nurses not answering the buzzers, patients not getting pain relief, elderly patients not being helped to go to the toilet. During the visit in the Emergency Assessment Unit, the Healthcare Commission visitors had to rescue one patient from falling out of bed and there was a tendency in the visit for the Healthcare Commission visitors to be escorted rather than being allowed the free reign* [sic] *of the Trust.*[300]

8.259 By this time, the Trust was authorised as an FT and the WMSHA had legally ceased to have an oversight role in relation to it. However, it retained a responsibility to oversee the quality of care being offered to NHS patients in its region. It could discharge that responsibility via the PCTs commissioning the service. Quite properly, although there was some questioning by Dr Wood of the WMSHA's continuing role, by mutual agreement communications between the HCC and the WMSHA continued.

8.260 However, in spite of the potential gravity of the concerns being pursued by the HCC, particularly following the findings of its unannounced visit, the WMSHA appears to have confined itself to the role of interested spectator, standing ready to assist the Trust in defending itself by reference to the coding issue.

8.261 On 6 March 2008, Dr Shukla circulated to colleagues a briefing note she had received from Dr Moss of a meeting she had had with the HCC the day before.[301] In the email chain which followed, Mr Allen responded:

298 RS/42 WS0000019054
299 Shukla WS0000018561, para 131
300 RS/41 WS0000019051–052
301 RS/43 WS0000019059

I'm confused about this entire HCC engagement. First, it was clearly about the mortality data, then it seemed as though this was only the starting point and the real concern was evidence of poor clinical practice and nurse staffing, now it seems to be switching back to the Dr F data.

If it really is about the data issues, then we should be doing everything we can to support MSGH.[302]

8.262 Ms Bower commented:

Talking to the HCC today, I think it's still about both, but agree we need to support them, is there anything else we should be doing?[303]

8.263 Mr Allen then added:

MSGH aside, I'm concerned about a precedent being set whereby Dr F data is used as the main criterion for initiating reviews. The data is insufficient justification in itself and let's not forget that this is a company which is selling "improve your mortality rating" services to Trusts. Does HCC not see the conflict here?[304]

8.264 Dr Shukla then reported a conversation she had had with Dr Wood who had made it clear that the HCC did not accept the Trust's view that the high mortality rates were due to poor coding. Dr Shukla asked colleagues to note that the HCC were undertaking their own analysis after which they would make a decision.[305]

8.265 On 13 March 2008, Dr Wood emailed Dr Shukla to inform her confidentially and in advance of a public announcement that the HCC had decided to launch a formal investigation.[306] This was to be followed by the formal announcement on 19 March.

8.266 It was therefore clear, or should have been clear, to the WMSHA, at this stage, that the HCC's concerns were not, in its view, satisfactorily answered by reference to coding quality. By this time, in addition to the HSMR, it was clear that the HCC was looking at a picture formed from:

- The HSMR data, which Dr Shukla had recognised could not be entirely explained by coding;
- Alerts, some of which could be so explained, but not all;
- A series of individual complaints raising concerns about the standard of care;

302 RS/43 WS0000019059
303 RS/43 WS0000019058
304 RS/43 WS0000019058
305 RS/43 WS0000019057
306 RS/46 WS0000019088

- Findings of an unannounced visit by the HCC showing the provision of an inadequate and in some respects unsafe service;
- The fact that the HCC was sufficiently concerned to take the unusual step of launching a formal investigation.

8.267 In addition to this, it was known to the WMSHA that there were as yet unresolved staffing issues as evidenced by the ongoing skill mix review.

8.268 If ever there was a set of circumstances to prompt any organisation charged with overseeing the safety and quality of service provided to take action, as opposed to continue to rely on others, then surely this was it.

8.269 On 17 March 2008, Dr Shukla received an analysis of mortality from Dr Kesh Sidhu, a consultant in public health medicine working for an unrelated PCT, whom she had asked to analyse mortality in emergency admissions across the region.[307] While he did not discover an unduly high overall mortality, he did find increased mortality associated with particular diagnostic groups and particular surgeons.[308] As Dr Sidhu's work was developmental, Dr Shukla did not feel concerned by the results.[309] However, she did share them with the Trust's Medical Director and she believes that the Trust concluded these figures were also due to coding inaccuracies.[310] Dr Sidhu entered into a discussion with the HCC about his methodology.[311] Whatever questions there were over his methods, Dr Suarez had the impression that his work was more useful than the Dr Foster data.[312] What was significant was that, by asking Dr Sidhu to conduct this work, developmental though it was, Dr Shukla was manifesting her continuing concern that the HSMR figures might not be wholly explained by coding.

8.270 In mid March 2008, following contact between the HCC, the WMSHA and Dr Mohammed and Professor Lilford about data, the WMSHA raised with the HCC the possibility of the WMSHA conducting a case note review of a sample of the low-risk patients who died, similar to that which had been carried out for the SHA at George Eliot Hospital.[313] The offer was made to assist the HCC with its investigation. The HCC did not take this up. As Dr Wood explained:

307 Shukla WS0000018562, para 118; RS/44 WS0000019063; T69.58–59
308 Shukla WS0000018563, para 119; RS/44 WS0000019063
309 Shukla WS0000018563, para 120
310 Shukla WS0000018563, para 119; T69.61–62
311 RS/45 WS0000019073–74
312 Suarez T59.149–150
313 Shukla WS0000018564, paras 123–124

We did have reservations about working jointly with the SHA on the further analysis of outcomes or case note reviews. Since the terms of reference covered governance arrangements with the local NHS, the SHA was also under scrutiny. We also considered we had sufficient expertise in-house and could call on our regular sources of expert help if required.[314]

8.271 As a result of this discouragement, the WMSHA decided not to proceed. Dr Shukla explained that:

When the HCC decided not to take the WMSHA up on this offer, we thought that it would not be proper to proceed with the review as the HCC had primacy of role in these circumstances. We were at pains to cooperate with the SHA, not to compete with them.[315]

8.272 Given that the purpose of its offer was to assist in the investigation, the WMSHA could have come to no other conclusion.

8.273 On 20 and 22 May 2008, the HCC conducted an inspection of the Trust's A&E, giving the HCC much cause for serious concern as described in *Chapter 1: Warning signs*. The findings were communicated to the WMSHA, among many others by being copied into the letter by Dr Wood to the Trust Chief Executive on 23 May. The reason Dr Wood wrote as she did was that:

This was an occasion where the risks to patient safety required immediate attention and we flagged those up for action straight away.[316]

8.274 Dr Shukla agreed that at this time there were clearly obvious concerns regarding the A&E department at the Trust. The WMSHA Chief Executive and Finance Director had been in discussions with the PCT about financial assistance to increase clinical and nursing support to the A&E. Around this time, Dr Shukla and Mr Blythin also approached a nearby FT and the DH for help in sourcing senior clinicians, but without success. In the end, the SHA secured support from the University Hospital of North Staffordshire NHS Trust.[317]

8.275 Further confirmation of the dire state of the Trust's A&E came in June, if confirmation were needed, from the peer review of children's services conducted by the regional peer review team (see *Chapter 1: Warning signs*). This review, surprisingly, was carried out by the team in ignorance of the HCC's findings in May. Although housed within the SHA and corresponding on the SHA's notepaper, it does not appear that anyone at the SHA was copied into Ms Jane

314 Wood WS0000025062, para 144
315 Shukla WS0000018564–5, para 125
316 Wood WS0000025057, para 126
317 Shukla WS0000018566, para 132

Eminson's letter to the Trust of June 2008, which highlighted peer review findings to the effect that there were some areas of: "immediate risk to clinical safety or clinical outcomes".[318]

8.276 The final report of the peer review was shared with the SHA in October 2008.

Strategic Health Authority attitude to the investigation

8.277 There were indications in evidence that the SHA regarded the HCC investigation with suspicion, doubting its justification. There were times when this appears to have been expressed aggressively.

8.278 Mr Peter Shanahan took over from Ms Bower as the interim WMSHA Chief Executive in August 2008. His concern, as expressed to the Inquiry, was that the HCC did not share sufficient information with the SHA to enable action to be taken, and that they effectively had to await the publication of the HCC report to be able to act on any concerns. This, he strongly implied, took too long:

> *For me, the most worrying issue about the HCC review process is that it took 14 months from when the HCC went into the Trust until they produced their report. During that time, the HCC would not tell us anything or share any results. As a result, neither the SHA or the PCT were able to take action to improve services earlier.*[319]

8.279 In fact, as he acknowledged in his oral evidence, they had received Dr Wood's letters expressing the HCC's concerning findings. As a result of those, a weekly monitoring of the Trust's A&E rota was introduced. He also told the Inquiry that the SHA had sought and received an assurance from the HCC that the A&E did not need to be closed.[320]

8.280 While it is clear that some degree of monitoring was instituted by the WMSHA, and further action was taken by the PCT (see *Chapter 7: Commissioning and the primary care trusts*), the general approach of the WMSHA appears to have been to await events, believing that the HCC was motivated principally by a view of mortality statistics that the WMSHA viewed with considerable suspicion. In an HCC record of its interview with Mr Shanahan, he is noted to have said:

318 CJE/33 WS0000023622
319 Shanahan WS0000020520, para 91
320 Shanahan T76.10

The interviewer informed the interviewees that the Healthcare Commission had recently written to the Trust with regards to the Dr. Foster HSMR of 127 and the fact this had never been the reason for, or the focus of, the Healthcare Commission's investigation. At this point in the interview discussion, Peter Shanahan read out extracts from the Terms of Reference for the Healthcare Commission's investigation, and said it was obviously all about mortality. The interviewer replied by informing him that yes it was about mortality, but not the Dr. Foster HSMR figure, to which Peter replied by saying that there was general confusion in the NHS with regards to the relationship between Dr. Foster and the Healthcare Commission and that Dr. Foster are citing the Commission in marketing techniques when attempting to sell their software to Trusts. The interviewer informed that the analysis for the investigation was separate and independent from Dr. Foster, to which Peter replied that there is a general view that people do not know where Dr. Foster ends and the Healthcare Commission starts. He also said that he thought there was a very high false positive rate for a lot of the Dr. Foster alerts.[321]

8.281 Mr Shanahan acknowledged in his oral evidence that, in fact, the periodic letters to the Trust from the HCC, beginning with the letter regarding the A&E Department, which had been copied to the SHA, had provided significant information about the quality of care at the Trust during the course of the investigation.[322]

8.282 In August 2008, Mr Yeates shared with Mr Blythin of the WMSHA one of the HCC's requests for information, which was meant to be confidential to the investigation. Indeed, he had sent it to Mr Blythin marked "sent in confidence".[323] Mr Nigel Ellis described this as "not appropriate".[324]

8.283 In a telephone call with Ms Anna Walker, Chief Executive of the HCC, in October 2008, Mr Shanahan criticised the conduct of the investigation by Dr Wood. In particular, he was concerned at the length of time it was taking as it was "dragging down" the Trust's reputation. Ms Walker responded that, while she understood the concerns, the quality of the investigation was more important than the exact time it was finished.[325]

8.284 This approach was continued in the WMSHA's response to the draft extracts of the HCC report on which comment was invited. The WMSHA was first sent a draft extract on 18 December 2008 by Dr Wood.[326] This was short, about six pages in length, and contained those parts of the draft most closely affecting the SHA. Mr Shanahan returned the SHA's comments by letter on 9 January 2009,[327] focusing comments mainly on matters of detail. On 29 January 2009,

321 STA/14 WS0005000318
322 Shanahan T72.185
323 NE/51 WS0000028269
324 Ellis WS0000027782, para 128
325 AW/36 WS0000030014
326 PWS/19 WS0000020825
327 PWS/18 WS0000020803; the letter is erroneously dated 9 December 2009

Dr Wood sent him a further draft extract. Again it was largely restricted to matters material to the SHA and amounted to no more than six pages of text.[328]

8.285 On 3 February 2009, Mr Shanahan wrote to Dr Wood complaining that the draft findings were not supported by evidence, and complaining about the fairness of the process. On the same day, he escalated this complaint in a letter to the HCC Chief Executive, Ms Walker. In both letters, he argued that the HCC had no evidential basis for the assertion that the WMSHA had been too easily reassured by the Trust with regard to its high HSMR.[329] The HCC changed the wording to remove the criticism and replaced it with a factual statement that the SHA has been reassured by the Trust.[330] In fairness to Mr Shanahan and the WMSHA, it does not appear that they were sent a very complete extract containing the evidence on which findings were based. Accordingly, it may well not have been apparent to them just how serious the concerns were that had been unearthed at the Trust. Their critical response to the extracts they were sent has to be seen in that context. Their reaction to the report as a whole has been markedly different. However, the issue with their response is that there was no sign of deeper reflection by the WMSHA about the attitude it had displayed throughout the investigation, given what it knew about the developing concerns harboured by the HCC: one of general scepticism about HSMRs, failure to realise the significance of the patient complaints received, and inadequate action to look for clinical explanations for the unexpected outcomes.

8.286 Other action taken included the preparation by Mr Allen of a paper criticising the HCC's methodology in relation to mortality statistics.[331]

8.287 These incidents suggest that the SHA allowed its scepticism about the HSMR to lead to a mistrust of the process being undertaken by the HCC. At times, as exemplified above, it gave the appearance of being an advocate for the Trust rather than a partner in an enterprise to protect patients from harm.

8.288 Mr Shanahan sought to explain the reasons for the apparently passive reaction to alarming events on the part of the SHA:

> *Q. Do you accept now that there was information which should have been available to the SHA if the SHA had been looking at it, which might have revealed concerns about this hospital?*
>
> *A. On reflection, yes.*
>
> *Q. With the benefit of hindsight, can you explain why the SHA didn't pick up on those various pieces of information and pull them together?*

328 PWS/17 WS0000020805
329 PWS/25 WS0000020854–56
330 PWS/26 WS0000020858
331 PWS/27 WS0000020864–6

A. ... having looked at the transcripts over the last few weeks, it's the information flows were into individuals, rather than into the organisation, and ... I don't think the organisation had a way of actually pulling those together so that there was a single source of information that everyone understood, ... so that everyone was on the same page, in terms of what was known.[332]

Positive steps that were taken by the West Midlands Strategic Health Authority

8.289 Following the authorisation of the Trust as an FT, the SHA's role was diminished in that, at least in theory, there was no scope for any form of direct intervention. However, the WMSHA drew the Inquiry's attention to the assistance and support it did give to the Trust during the year of the HCC's investigation.

- Advice and support was given to Dr Moss, Director of Nursing at the Trust, and to Mr Yeates. Mr Blythin told the Inquiry that, following the outcome of the staffing review, he maintained regular contact with Dr Moss to assist with the recruitment of further staff and planning, and implementing improvements in the interim.[333] He attended meetings with Dr Moss and Ms Sawbridge, of SSPCT, as on 9 July 2008, to discuss progress on nurse recruitment. In an email to Ms Bower the following day, he concluded:

 The meeting was constructive and I was able to establish that although the PCT remains concerned about the overall situation and A&E in particular, there is a level of confidence in the work the Trust is undertaking to improve things.[334]

- Mr Blythin also approved an allocation of around £283,000 on behalf of the WMSHA from the Workforce Deanery budget to the Trust, to support "a range of initiatives".[335]
- Dr Moss recalled that she tended to speak to Mr Blythin, either on the phone or face to face, and that he was "good at making suggestions which were usually practical and sensible". She did not recall that he ever raised any concerns about the work that she was doing. Dr Moss thought that, although she would have expected contact with the SHA to have been scaled down following the Trust's attainment of FT status, in fact the contact "got stronger" at the time of the HCC investigation. She "certainly found it useful ... to have access to discuss various matters".[336]
- The WMSHA also engaged with the Trust in response to the HCC review of children's hospital services (conducted in 2008), in which the Trust was rated as "poorly performing". The WMSHA staff met with the PCT to agree priorities for action and the required timescale.[337]
- The WMSHA introduced into the Trust two senior SHA operational managers to assist in providing operational leadership and support.

332 Shanahan T76.9
333 Blythin WS0000019674–5, para 137
334 Blythin WS0000019681–82, para 162; PB/34 WS0000020083
335 Blythin WS0000019682, para 164
336 Helen Moss WS0000009537–38, paras 233–234
337 Allen WS0005000179–80, para 108–112

8.290 However, although the WMSHA did increase the level of oversight following the announcement of the HCC's investigation, it remained content to rely on the PCT as commissioner to monitor the Trust's performance and improvement directly, as Mr Allen made clear:

> *By this stage* [in late 2008]*, our view was that the PCT was effective in holding Mid Staffordshire to account for performance in A&E and it was clear that they were meeting with the Trust on a regular basis. We still received regular reports from the PCT on this and were assured that the PCT were doing everything they could to manage the issue locally.*[338]

8.291 For example, in June 2008, the Trust commissioned a team from the Heart of England NHS Foundation Trust to look at their urgent care systems, and a report was produced including recommendations. Mr Allen did not see or request a copy of the report, because he was assured that the PCT was fully engaged on the follow-up.[339]

8.292 Some explanation for this may have been provided by awareness within the SHA of the pressures on the Trust at the time. On 8 August 2008, Mr Blythin received a telephone call from Mr Yeates in which he expressed his concerns about the level of scrutiny the Trust was under and the burden it was placing upon his staff. This position was reiterated in an email on the same day.[340]

8.293 It has also been suggested that the WMSHA was "entitled to gain some reassurance as to the safety of patients" from both the HCC's presence at the hospital (and concomitant scrutiny), and from a press release issued by the HCC in September described by Mr Shanahan as "quite positive about progress made the Trust has made".[341] The release stated that the Trust had improved medical staffing levels and increased the numbers of nurses in A&E. However, the HCC also said that further recruitment would be required for staffing to reach recommended levels, and made clear that the concerns that prompted the investigation were far broader:

> *The investigation is ongoing and will continue to look at other aspects of emergency care, including the care and treatment provided on wards that take patients as emergencies.*

8.294 The press release urged continued attention would be required to maintain staffing levels.[342]

8.295 There was no basis on which the WMSHA could conclude that the press release justified a reduction in the concern or scrutiny to be directed at the Trust. The statement was clearly

338 Allen WS0005000176, para 97
339 Allen WS0005000176, para 95
340 Blythin WS0000019683, para 166; PB/37 WS0000020093
341 CLO000000326–7 SHA Closing submissions, para 32; Shanahan T76.10–11
342 DH00990000108–9

limited to specific instances of improvement within the context of a far broader investigation into patient safety issues raised by the HCC. It was also explicitly conditional on continued scrutiny, and must be considered alongside the wealth of other available evidence capable of prompting further concern.

8.296 The overall position therefore was that the WMSHA, while offering support in a practical sense, was not in a position to lead direct performance management of the Trust as an FT and in any event felt reluctant to do more given the level of scrutiny to which the Trust was already being subjected. What it could have done was to have taken a more direct interest in the commissioning relationship via its oversight of the PCT. By whatever route, there was a need, in the interests of the patients, for joint action by all those in a position to take it. While some steps were taken (see above), the impression given has been one of waiting to see the outcome of the investigation rather than to accept that there was a current fundamental crisis giving rise to risks to patient care.

West Midlands Strategic Health Authority support for Mr Yeates

8.297 Mr Yeates told the Inquiry that he began to consider his position once he had become aware of the likely content of the HCC report, around the time he was interviewed in October 2008.[343] Once he knew what would be in the report, he had discussions with the WMSHA regarding his future. He described these discussions as positive:

> *The SHA were keen to keep me onboard and said they would move me somewhere else if necessary.*[344]

8.298 Mr Yeates believed that this offer, made by Mr Shanahan, remained open after the publication of the draft report, in December 2008, and up until he was asked to resign by the Trust's Interim Chair, David Stone.[345]

8.299 Mr Shanahan gave evidence to the effect that there had been an initial period, from late 2008 up to early 2009, when there had been discussions about enabling Mr Yeates to move "sideways" into another position within the NHS:

> *There was never a specific employment opportunity for Martin. Martin had asked us, probably late 08 through into early 09, whether or not we could facilitate, I think a secondment to another organization. And I think we had some discussions. But clearly when we were sighted on what the report contained, that wasn't a credible option.*[346]

343 Yeates WS0000074963, para 134
344 Yeates WS0000074965, para 139
345 Yeates WS0000074966, paras 140–142
346 Shanahan T76.47

8.300 By February/March 2009, Mr Yeates' position had become untenable.[347]

8.301 In a document dated 12 February 2009, which was circulated within the DH and submitted to the Secretary of State, the Director General of NHS Finance, Performance and Operations, Mr David Flory, noted the following:

> *The SHA's view is that the chief executive will also leave his post. The SHA is in discussion with him about this. A likely scenario is that he will move to another post in the system. This seems reasonable to me in the particular circumstances of the case.*

8.302 Mr Flory told the Inquiry that he had been wrong about this and that his judgement changed "quite soon afterwards".[348]

8.303 The practical reality is that the SHA had no role in determining Martin Yeates's immediate future. That role was the role of the FT Board and Monitor.

Changes made by the West Midlands Strategic Health Authority since the Healthcare Commission report

8.304 Following publication of the HCC report, an internal look-back exercise was undertaken by the WMSHA.[349] As Professor Cumming said:

> *Initiatives ... have been introduced in the West Midlands in response to the tragic events at Mid Staffs ... there were clearly flaws in the system. What we have done in the SHA is to try and identify those flaws and to try and put different initiatives in place to – to prevent it ever happening again.*[350]

Patient safety dashboard

8.305 The WMSHA now uses a multi-faceted patient safety "dashboard" to monitor trust performance, which seeks to replace the previous, high-level indicators with multiple data feeds, incorporating both hard and soft information. These include online access to 208 comparative quality of care indicators compiled by the independent provider CHKS, quality measures developed by the SHA's clinical leads and other sources of information such as SUI reports.

347 Shanahan T76.46
348 Flory T121.153–154; DH00120000312
349 Cumming WS0000016702–3, paras 148–149; IRC/70 WS0000018021–4
350 Cumming T67.203–4

8.306 The dashboard has indicators under five main headings:

- Inequalities;
- Quality;
- Patient safety;
- Productivity;
- Primary care.

8.307 The dashboard acts as a warning mechanism, designed to prompt further investigation by the SHA. As Professor Cumming explains:

> *No individual indicator on the dashboard is perfect or guaranteed to identify problems. Collectively, however, they are an effective mechanism for triggering further investigation.*[351]

Appreciative enquiries

8.308 Appreciative enquiries, established in July 2009 as a direct result of events at the Trust, are a system of formally structured visits designed to indicate potential issues relating to the quality of services at providers. They are instigated by the WMSHA (through the PCTs for FTs) where it has significant cause for concern. The visits are conducted jointly by the WMSHA and the PCTs, with an external clinician and the invited local CQC representative, and the visit team speak to patients, members of staff and carers. Feedback and findings are shared with the trust, which is asked to respond to any issues raised. A detailed report is prepared and, if required, an action plan to address any issues found is prepared. The WMSHA has liaised with PCTs in order to equip them to undertake the visits, and draft guidance has been produced. Professor Cumming described the process as one of "rigorous quality assurance visits".[352]

8.309 These initiatives do show that, following the HCC report, the WMSHA began to demonstrate a deeper understanding of the need to monitor quality, as well as finance, to ensure better and more thorough communication and sharing of information with regulators and other parts of the NHS system, and to take a more proactive and questioning role than it had in the past. Its ability to continue to develop such measures has of course been cut short by the abolition of the SHAs.

351 Cumming WS0000016709–10, paras 168–172
352 Cumming WS0000016711–12, paras 174–176

General conclusions

Role in overseeing safety and quality

8.310 The role expected of SHAs was challenging in a time of extensive reorganisation, financial challenge, and reduction in staff and organisational resources. Their task was not made easier by a degree of confusion with regard to the extent to which SHAs were expected to address concerns about quality and safety.

8.311 In spite of these difficulties, which were not of the SaSSHA's or the WMSHA's own making, the evidence shows that the WMSHA did not explicitly relinquish an involvement in the performance management and oversight of provider trusts, but, on the contrary, was willing to intervene, forcibly if necessary. It did not proactively seek out quality and safety concerns, but it did seek to respond to concerns of which it became aware. Therefore, it retained the capacity – and responsibility – to respond to concerns in relation to patient safety and quality of care, and to ensure these were being addressed effectively when matters of concern were drawn to its attention.

8.312 The WMSHA, in its closing submissions, argued that it had to be borne in mind that the strategic role was just as important as the performance management role.[353] This may be so, but that does not excuse it from doing the latter properly, particularly where failure to do so might lead to strategic issues.

8.313 A proper and reasonable strategic direction taken by the WMSHA was the attempt to develop metrics focused on patient safety. However, the effect of this initiative was diluted by the unexpected time the project took, and because the original idea of outcome-based measures was largely replaced by more indirect ones. The WMSHA recognised correctly that there was a gap in safety monitoring that required a means of measuring safety. However, at a time when the metrics were not ready to be implemented and incorporated into contracts and PCTs had few, if any, other tools available to them to undertake their own monitoring, the SHA gave insufficient consideration to the implications of this delay in developing its own metrics for the performance of its duties.

8.314 The WMSHA also pointed out to the Inquiry that the Trust was but one of many organisations in the region with problems. Those at other organisations were perceived to be more serious. The WMSHA was relatively small and had a lot to cope with. This again is not an excuse for inaction. Either the SHA had the resources and ability to do the entire job that had been delegated to it, and it failed to carry out that job, or it did not have the resources and ability, and failed to alert those responsible to the problem. There has been no evidence that the SHA at any time claimed it was under-resourced or that there was a risk it could not fulfil its responsibilities.

353 CL0000000022 SHA closing submissions, para 43

8.315 The story of the WMSHA's handling of concerns raised in connection with the Trust is more a matter of a collective judgement being made that there was nothing of concern warranting exceptional action, than it was of having insufficient resources to conclude that such action needed to be taken. It seems likely that, had its officials decided that the high HSMR warranted serious investigation of clinical quality at the Trust, it could have arranged for that to be done, even if it could not undertake the task itself. It could, and probably would, have made enquiries that would have brought together more of the information that we now know was available for the asking, to add to the concerning picture. In the end, it was not the functional gaps in the system or a lack of resources that prevented the WMSHA and its officers from seeing there was a serious problem requiring exceptional measures. Instead, it was due to an overall culture in the system, which:

- Failed to be sufficiently sensitive to signs that patients might be at risk;
- Was too ready to place trust in provider boards and leadership without requiring the evidence to justify it;
- Was prepared to assume that others would share information showing concern and requiring action without being asked;
- Placed greater weight on positive signs than on negative ones;
- Was readier to defend providers in the system than to consider the implications of criticisms and concerns being expressed, if they were justified;
- Became far too remote from the patients they were there to serve.

Effects of reorganisation

8.316 The reorganisation of the structure of SHAs and their relationship with PCTs and providers in 2005–2006 appears to have been conducted without any assessment of the risks to patient safety or the quality of service posed by the process of change.

8.317 The change was intended to transfer a major part of the performance management role to PCTs, leaving SHAs to focus on strategic issues and performance management of the PCTs themselves. However, the SHAs' previous, more active role ceased before the newly formed PCTs were in a position fully to take over the function. The reconfiguration of PCTs and development of the concept of commissioning meant that there was a serious lack of connection between the understandings of PCT leadership and that of the SHA. This increased the risks attached to mutual misunderstanding about where a function was being performed, and widened the gap through which poor performance could pass unnoticed. Whatever steps were put in place to prevent a loss of control in the system, insufficient consideration was given by the leadership of the WMSHA to the serious risk of compromises to patient safety going unnoticed or uncorrected as a result of the changes being made. A more important strategic concern is difficult to imagine. In the West Midlands at least, the WMSHA failed to fill this strategic gap effectively. Given the absence of any suggestion in the evidence that this

SHA was exceptional in this regard, it was probably not alone in this failure and this is, therefore, a matter of defective implementation of policy by the DH.

8.318 There was no effective system for ensuring the transfer of information and knowledge from one iteration of the SHA to the next, in spite of the very substantial staff cuts that accompanied the change. Information about these matters was passed on in an ad hoc and sporadic fashion, but this cannot be regarded as an adequate arrangement in a reorganisation of this size. The DH, charged as it was with the implementation of the underlying Government policy in this regard, has a share of the responsibility for this omission, as has the SHA itself. However, it is unlikely that even the best of handover systems would have resulted in any clear concerns being transmitted about the Trust, because none appears to have registered with the SaSSHA.

Non-financial performance management and oversight of the Trust

Misplaced priorities

8.319 The underlying reason for the failure of the SaSSHA and the WMSHA adequately to seek out or address patient safety and quality concerns about service provision at the Trust, was a failure to give sufficient explicit priority to the protection of patients and to ensure that patient safety and quality standards were being observed there. There were warning signs of which they were unaware, partly through deficiencies of communication and partly through the reactive approach adopted. However, there were warning signs of which they knew and, indeed, followed up. In relation to these, the SHA generally did not consider the implications for patient safety of such concerns and the inferences to be drawn about the competence of the Trust's leadership. In common with the system as a whole at the time, the focus was unduly directed at financial and organisational issues, while losing sight of one of the central purposes of the service they were seeking to support – namely, to provide safe care to at least a fundamental standard.

Focus on targets

8.320 In *Shifting the Balance of Power: The next steps*, it was stated that:

> *[P]erformance management will give more attention to health outcomes and patient impact ...*
>
> *Process indicators that currently stand as proxies for outcomes will increasingly be phased out ...*[354]

8.321 As has been seen, the SHA approach to quality, even in 2005–2006, was still focused on measuring performance against the nationally created targets with little additional scrutiny

354 DH00060000024 *Shifting the Balance of Power: The next steps* (Jan 2002) Department of Health, para 3.8.6, p 23

of the underlying reasons why targets were not being met. This is unlikely to have been an approach unique to the West Midlands, but reflects the national preoccupation with financial control throughout this period. As has been said many times, in principle there is nothing objectionable to targets for matters such as waiting times when these are understood to reflect public expectations.[355] The challenge is to ensure that they do not lead to the unintended consequence of a loss of focus on maintenance of patient safety and minimum quality standards.

8.322 This continued into 2007, even though recognition was increasing the need for more outcome based measures.

8.323 Not all attention paid to targets was unproductive. For example, the WMSHA reaction to the Maidstone and Tunbridge Wells report was to undertake a strenuous campaign to improve the performance of trusts in the region. It took a number of steps of a type that should also have been considered in addressing the mortality issues raised by the 2007 Dr Foster report.

Intervention on Accident and Emergency Department targets

8.324 Although steps were taken by the WMSHA to performance manage failures to meet the A&E target, little effective consideration seems to have been given to the possible reasons for those failures. What mattered was encouraging trusts to meet the target. At the Trust, it is clear that there were staff shortages and serious leadership issues lying behind this sort of problem. They were not detected. This weakness should not be considered to be satisfactorily addressed merely by removing the focus from targets. Just the same attitude could result from an excessive focus on any set standard, whether directed at process or outcome. Any one-dimensional approach will run the risk of producing perverse, unintended and undesired results for patient safety, because no system will be perfectly designed to ensure patients are automatically protected.

Failure to recognise significance of staffing shortages and training deficiencies

8.325 On more than one occasion, the SHA was made aware of concerns about the number and skills of Trust staff, but these seem to have been addressed as something entirely separate from issues about safety and quality. Like the Trust, and possibly the system as a whole at the time, staffing was considered relevant to finance and obligations to balance the books. There were – and remain – no accepted measures in general use for determining the staffing requirements for a safe service. This is no reason for failing to focus on whether an acknowledged shortage of staff, or proposed cut in establishment, carries risks for patients and indicates a need to adjust the service provided. This failure to link staffing issues with patient safety may explain the lack of interest or urgency in looking at these issues when they were raised about the Trust. As a result, there were a number of missed opportunities to consider the significance of information in the SHA's possession.

355 See, for example, Flory T121.52–54; Bradshaw T116.156–157

Failure to act on children's service peer reviews

8.326 The criticisms made of the WMSHA in relation to the children's service peer reviews are fully set out above and in *Chapter 1: Warning signs*. The failure was both in strategy and in performance management. In spite of being associated with a peer review system, which was being effectively run by Ms Eminson, there was no consideration of how this work should be used and how those responsible for addressing concerns raised should be identified. That not having been done, the performance management role remained with the SHA. This is a graphic example of the organisation as a whole, and at least some of its senior staff, failing to do more than go through the motions. If the safety of patients, in this case vulnerable children, had been at the forefront of their minds instead of focusing almost exclusively on performance targets, it is difficult to see how the 2006 report could have been ignored, especially given its echoes of problems identified four years previously by CHI. The failure meant that the WMSHA Board was left unaware of the damning criticisms in the report, some of which were relevant not only to the care of children, but all patients, and brought into question the competence of management. The WMSHA Chair was left in ignorance of information that might well have altered her judgement of the Trust's response to the almost simultaneous HCC children's service review.

Failure to act on the Gillian Astbury Serious Untoward Incident

8.327 The analysis, both in the *Chapter 1: Warning signs* and above, shows that an important opportunity to detect and act upon the serious systemic failings in the Trust was missed because no one at the WMSHA seems to have read or appreciated the significance of this SUI. Although a reasonable system had been put in place in theory, it was not being applied properly in practice, not just in this case, but in the case of thousands of SUIs throughout the region. This may well have been, in part, due to the small number of staff available and the many other tasks demanding their attention. However, underlying this failure was probably the undue reliance that was habitually placed on provider trusts and their Boards to take effective action to protect patient safety. Even a "light touch" approach to oversight and performance management and resort to "exception" reporting should have – and did – require attention to be paid to SUIs, which, by definition, were events giving cause for concern. They were evidence that an event may have occurred at a provider, indicating that trust in their management might not be warranted. Instead, the prevalent presumption that good practice would be followed was allowed to persist.

Reaction to high Hospital Standardised Mortality Ratio

8.328 A detailed description of the WMSHA's reaction to the Trust's high HSMR appears in *Chapter 5: Mortality statistics*. The evidence shows that there was a greater willingness at the WMSHA, as elsewhere in the system, to accept such statistics as reassuring when they were "low", than to accept that they were a matter of concern when "high". This is also another example of an undue willingness to rely on a Trust Board and its assurances without taking any adequate steps to rule out the inference, if properly drawn, that the figures could, at least in

part, have been due to widespread poor care at the Trust. The result was that the WMSHA concentrated on finding means to attack the methodology, rather than to take steps to protect patients from risk and to ensure that past deficient treatment was brought to light and appropriate remedies offered to affected patients and their families.

8.329 This was not an instance where the WMSHA can seek to excuse itself by suggesting the matter was one for which the PCT was responsible. They recognised and accepted that it was a matter within their responsibility for patient safety and good governance, through their direct interaction with the relevant trusts and the commissioning of research. This is not to say that it was wrong to investigate the methodology or to take steps to consider its true significance. Clearly, there was more than one view that could be taken about such matters, as has been shown by the debates of the recent national review of HSMRs, chaired by Ian Dalton, which has proposed the alternative of a new standard methodology for a Summary Hospital-level Mortality Indicator (SHMI).[356] What was wrong, however, was to proceed as if this was the only matter of substance to consider. Until such time as it could be said with confidence that being an outlier for HSMR could not reasonably mean that there were associated concerns for patient safety and quality of care, it should have been assumed that there was at least a risk that this was so, and urgent steps taken to investigate that hypothesis. At a minimum that required some form of review of cases within the diagnostic groups at each provider showing high HSMRs in that group. Such a review should have included not only a review of notes, but some contact with deceased patients' families to establish whether they had any concerns about the care their relative received. An opportunity arose to consider this sort of action when the SHA was made aware by Dr Foster Intelligence at the meeting in August 2007 of the detailed picture at the hospitals in its region. This was not done.

8.330 Unfortunately, there was a failure to adequately perform the task the SHA took on, or to adopt any thought-out plan to protect patients. Instead, the focus seems to have been on attacking the HCC for not sharing its concerns earlier, demanding clarity where none might, in fact, have been possible, and questioning the justification for the HCC acting on the implications for patients by investigating them. Again, faults in inter-organisational communication may have existed: they are not a reason for failing to take the necessary action to protect patients.

356 Keogh WS0000065301–2, paras 147–149

Lessons for the future

8.331 It may be thought that an analysis of the faults of an SHA is now redundant, because they are now being abolished. This could not be further from the truth. Whatever the changes made under the recent reforms, or that might be made in the future to the structure of the NHS, a performance management and strategic oversight function will reside somewhere in the system. As at the time of writing this report, the announced intention of the NHS Commissioning Board is to have regional offices in similar numbers to those of the SHAs that have been abolished. Such an oversight function may be given to these. It may be given, in whole or in part, to commissioning groups, or clusters of such groups, or it may be retained by the NHS Commissioning Board itself.

8.332 Wherever lies the responsibility for performance management and strategic oversight of services provided to patients, it is important that the relevant organisation or organisations, and those who lead them, have the capacity, resource and competence at least to detect and act on systemic failings at provider level. Further, and much better, they must also have the sensitivity to be able to prevent deficiencies in meeting fundamental safety and quality standards turning into systemic failure. This can only come with a change in culture, which in turn requires a new attitude to patients; an attitude that prioritises their safety and the identification and achievement of fundamental standards of care. This focus need not detract from the other obligations of a performance manager with regard to finance, and strategic responses to the health needs of communities. However, there is little point in achieving perfectly balanced books and a comprehensive plan for healthcare to meet the needs of a population if dangerous practice is allowed to persist. No longer should it be a sufficient excuse for failure of care to patients to say at a strategic level that it was the responsibility of a provider board or a local commissioner to prevent this. Put very simply, if information indicating a concern for patient safety and quality comes into the possession of a strategic organisation, it needs to intervene, and keep intervening until the issue is resolved. This does not mean that the leader of a regional office is obliged personally to take over the management of every patient complaint, but it does mean that such leaders should not presume that others are performing their tasks properly. The whole point of performance management and oversight is to address the cases where the expected system is not working correctly or effectively.

Summary of recommendations

Recommendation 139

The first priority for any organisation charged with responsibility for performance management of a healthcare provider should be ensuring that fundamental patient safety and quality standards are being met. Such an organisation must require convincing evidence to be available before accepting that such standards are being complied with.

Recommendation 140

Where concerns are raised that such standards are not being complied with, a performance management organisation should share, wherever possible, all relevant information with the relevant regulator, including information about its judgement as to the safety of patients of the healthcare provider.

Recommendation 141

Any differences of judgement as to immediate safety concerns between a performance manager and a regulator should be discussed between them and resolved where possible, but each should recognise its retained individual responsibility to take whatever action within its power is necessary in the interests of patient safety.

Recommendation 142

For an organisation to be effective in performance management, there must exist unambiguous lines of referral and information flows, so that the performance manager is not in ignorance of the reality.

Recommendation 143

Metrics need to be established which are relevant to the quality of care and patient safety across the service, to allow norms to be established so that outliers or progression to poor performance can be identified and accepted as needing to be fixed.

Recommendation 144

The NHS Commissioning Board should ensure the development of metrics on quality and outcomes of care for use by commissioners in managing the performance of providers, and retain oversight of these through its regional offices, if appropriate.

Chapter 9
Regulation: the Healthcare Commission

Key themes

- The standards the HCC was expected to enforce, focusing on processes rather than outcomes, were not entirely accepted by its leadership.
- The HCC could not cope with the complaints function it was expected to perform and was not adequately resourced to carry this out.
- The process of compliance assessment relied to a large extent on self-declaration.
- Communications between the HCC and other relevant organisations was inadequate.
- The HCC investigation of the Trust was in the end thorough and effective, but although information about concerns were periodically conveyed to other organisations, no recommendations for immediate intervention were made in spite of the length of time the process took and of having no such powers of its own.
- What the central investigation team exposed in itself proved the effectiveness of this means of regulatory enforcement.

The creation of the Healthcare Commission

The Healthcare Commission replaces the Commission for Health Improvement

9.1 The Healthcare Commission (HCC) succeeded the Commission for Health Improvement (CHI), which had a short life from 2000–2004. Professor Sir Liam Donaldson told the Inquiry that CHI was abolished largely because of the number of complaints from NHS chief executives that CHI inspections were so frequent and burdensome that they had little time to prepare for anything else.[1]

9.2 According to Professor Sir Ian Kennedy, the Chair of the HCC, the demise of CHI was caused by it not having "endeared itself to the politicians as it showed itself to be too independent".[2]

1 Donaldson WS0000070126, para 72
2 Kennedy WS0000025844, para 34; T77.12–13

9.3 It is not part of the task of this Inquiry to determine the correctness of that statement, but the perception that this is a problem facing regulators in the health sector is relevant. Regulators whose independence is open to question, even if unfairly, may lack the credibility and authority to gain public confidence and be regarded as an effective force by regulated entities.

9.4 In any event, another reason for change was the recommendations of the Bristol Inquiry.

The recommendations of the Bristol Inquiry

9.5 The Bristol Inquiry, which Professor Kennedy chaired, ended in a wide-ranging report of great significance for the health service as a whole, not just for paediatric heart surgery. Professor Kennedy's report[3] made a number of recommendations for the creation and reform of healthcare regulation. The guiding principles underlying those recommendations for the service in general were that:

- *The complexity of the NHS as an organisation must be recognised.*
- *Patients must be at the centre of the NHS and thus the patient's perspective must be included in the policy, planning and delivery of services at every level.*
- *The dedication and commitment of NHS staff is and must remain at the core of the service.*
- *The quality of healthcare must include all aspects of care: clinical and non-clinical.*
- *Patient safety must be the foundation of quality.*
- *Systems of care, and facilities, as well as individuals, affect the quality of healthcare.*
- *Learning from error and mistakes, rather than seeking someone to blame, must be the priority to improve safety and quality.*
- *Openness and transparency are as crucial to the development of trust between healthcare professional and patient, as they are to the trust between the NHS and the public.*[4]

9.6 Professor Kennedy called for "consistency of direction", for the "legitimate needs of patients" to be at the centre of an NHS in which the professionalism and dedication of those working in the NHS were respected and harnessed for the good of patients.

3 Professor Kennedy was assisted by a panel of three, including Professor Sir Brian Jarman.
4 Kennedy WS0000025837, para 7; IK/1 WS0000025896, pages 255–256

9.7 In relation to safety, Professor Kennedy said this:

> *We are convinced that the only definition of quality in the context of healthcare which can be of real value has to be one which is all embracing. A first condition for achieving quality in healthcare is that the service is safe. Once safety, as a fundamental prerequisite, has been addressed, attention must turn to the pursuit of quality. In essence, this involves identifying what will enable the NHS to meets its own high objectives and values.*[5]

9.8 The matters which the report identified in this context were:

- Respect and honesty towards patients and their families;
- Competent staff who are always striving for improvement;
- Suitable facilities;
- Up-to-date medical knowledge;
- Mechanisms for assessing the effectiveness and value of treatment;
- Safe treatment, avoiding error and accident so far as possible;
- Treatment and care which are appropriate for and responsive to the patient's needs, available when needed, in good time and accessible;
- Responsibility for the quality of healthcare services resting with some identifiable person.

9.9 Professor Kennedy also emphasised that analysis of the quality of healthcare needed to go beyond a focus on the clinical skills of individual professionals as in the past, to look additionally at the systems by which care was delivered, and, importantly, the attitudes of staff, both clinical and non-clinical:

> *We are saying, in effect, that to secure care of high quality across the NHS, we can no longer overlook those elements of the service which go beyond technical skills and competence and beyond the systems in which they are practised. We have to care about attitudes, about respect and honesty, indeed about a partnership between patients and professionals.*[6]

9.10 With regard to regulation specifically, the report to the Bristol Inquiry recommended that:

- Regulation needed to be independent of the Department of Health (DH) and under a statutory framework that was itself as independent as possible from the DH:

 This is quite simply because it is not in the interests of the public or of patients that the monopoly provider should also set and monitor the standards of care;[7]

5 IK/1 WS0000025898, pages 257–258
6 Kennedy WS0000025837, para 7; IK/1 WS0000025899, page 258
7 Kennedy WS0000025837, para 8; IK/1 WS0000025902, page 261

- Regulatory bodies dealing with safety, quality and standards needed to be coordinated and their efforts aligned by an overarching system which removed duplication and stopped up "holes in the system":

 Only in this way will the fragmentation and lack of clarity about responsibility for regulating the quality of healthcare, which was such a feature of Bristol, be addressed. And by insisting on independence from Government, the systems to ensure safety and promote quality of healthcare will be made secure from the vagaries of passing political pressures ...

 Management must be for the Department of Health and exercised in every trust, but from the perspective of the patient, regulation is a different enterprise. It is there to protect them against all political weathers;[8]

- Standards and quality needed to be "the sole priority of the body responsible for them, not one of a number of competing priorities".[9]

9.11 The report identified weaknesses in both CHI and the National Institute for Health and Clinical Excellence (NICE) (which had been established as a Special Health Authority by the Government in 1999):

- They were not sufficiently independent;
- Neither body had power to enforce compliance with its reports;
- Both looked to the DH for membership resources and their agenda;
- A mechanism was needed to bring together the many regulators:

 A plethora of organisations, all with their own ambitions and anxious to defend their "territories", was one of the defining features of what happened in Bristol ... To bring together the various activities of these agencies, to ensure that issues are not missed, and to give some kind of strategic direction, some further mechanism is needed.[10]

9.12 It was recommended that a council for the quality of healthcare, with independent status, should be set up for this role in relation to the regulation of healthcare institutions, alongside the council already being set up for the same purpose with regard to the regulation of healthcare professionals.[11]

8 IK/1 WS0000025902, page 261
9 IK/1 WS0000025935, page 316
10 IK/1 WS0000025937, page 318
11 The latter body is now the Council for Healthcare Regulatory Excellence (CHRE).

9.13 The specific recommendations about healthcare systems regulations included that:

- One body, NICE, should be responsible for coordinating all action relating to the setting, issuing and keeping under review of national clinical standards;[12]
- There should be:

 ... a single, coherent, co-ordinated set of generic standards: that is standards relating to the patient's experience and the systems for ensuring that care is safe and of good quality (for example corporate management, clinical governance, risk management, clinical audit, the management and support of staff and the management of resources). Trusts must comply with these standards;[13]

- There should be one body responsible for validating and re-validating trusts: CHI. Other bodies concerned with setting and requiring compliance with generic standards should "fall within the authority of CHI" and be answerable to it.[14]
- There should, as part of CHI, be an office for information on healthcare performance that would be responsible for monitoring clinical performance.[15]

Legislative framework

9.14 The legislation setting up the HCC called the new organisation the Commission for Health Audit and Inspection, the acronym for which (CHAI) was confusingly close to its predecessor. Happily, confusion was avoided by the organisation adopting "Healthcare Commission" as its working title.

9.15 The HCC was created by the Health and Social Care (Community Health and Standards) Act 2003. The HCC was given the general function of: "encouraging improvement in the provision of health care by and for NHS bodies."[16]

9.16 Its more specific functions were:[17]

- To publish data relating to the provision of healthcare by NHS bodies;
- In each financial year, to conduct a review of the provision of healthcare by each NHS body and award a performance rating to each by reference to the standards devised by the Secretary of State;
- For the purposes of the above functions, to conduct inspections;
- To conduct reviews of the overall provision of healthcare by NHS bodies;
- To conduct reviews of the overall provision of particular kinds of healthcare;

12 IK/1 WS0000025962, page 452, recommendation 122
13 IK/1 WS0000025963, page 453, recommendation 130
14 IK/1 WS0000025963, page 453, recommendation 132
15 IK/1 WS0000025963, page 455, recommendations 146–147
16 Health and Social Care (Community Health and Standards) Act 2003, section 48(1)
17 Health and Social Care (Community Health and Standards) Act 2003, sections 49–52

- To conduct particular reviews, upon the Secretary of State's request.

9.17 In exercising these functions, the HCC was to "be concerned with":

> *(a) the availability of, and access to, the health care;*
>
> *(b) the quality and effectiveness of the health care;*
>
> *(c) the economy and efficiency of the provision of the health care;*
>
> *(d) the availability and quality of information provided to the public about the health care;*
>
> *(e) the need to safeguard and promote the rights and welfare of children; and*
>
> *(f) the effectiveness of measures taken for the purpose of paragraph (e) by the body in question and any person who provides, or is to provide, health care for that body.*[18]

9.18 Where the HCC, on undertaking a review, found "significant failings" in an NHS body in the provision of healthcare, it was obliged to report this to the Secretary of State and could make recommendations for the remedying of most failings.[19] In relation to a foundation trust (FT), it had a similar duty to report this to Monitor.

9.19 The HCC was given no direct enforcement powers; it was limited to making recommendations to the Minister and to Monitor, who had powers of direction and intervention. The absence of an ability to intervene directly to enforce standards inevitably weakened the effectiveness of the HCC as a regulator and meant that, in the case of NHS bodies under the control of the Secretary of State, there were no independently held powers of intervention and, in the case of FTs, the HCC was required to persuade another regulator to act.

9.20 While the HCC was independent, it was subject to the direction of the Secretary of State in a number of ways:

- In exercising any of its functions, the HCC had to have regard to such aspects of Government policy as the Secretary of State might direct. The functions under sections 48(1), 49, 51 and 53 (described in paragraphs 9.15 to 9.18 above) were, however, specifically excluded from the limitation;[20]
- Even there, its independence of action was potentially curtailed by Ministerial discretion; when the Secretary of State considered that the HCC was, to a significant extent, failing

18 Health and Social Care (Community Health and Standards) Act 2003, section 48(2)
19 Health and Social Care (Community Health and Standards) Act 2003, section 53
20 Health and Social Care (Community Health and Standards) Act 2003, section 130

properly to discharge its functions, he/she had the power to give it directions, which it was required to follow.[21]

9.21 A further challenge to the HCC, according to Professor Kennedy, was that the standards by which it was expected to rate organisations were prepared and published by the Secretary of State, not by the HCC itself.[22]

9.22 Professor Kennedy told the Inquiry that he was not involved in the creation of these standards, nor was the HCC afforded any specific role in this process.[23] Professor Kennedy referred to the core standards, as the National Standards of Care became known, as being passed down as "tablets of stone".[24] The evidence around this issue is considered below. It appears that he was at least formally consulted even if his views were not accorded any specific priority.

The birth of the Healthcare Commission

9.23 Professor Kennedy was appointed Chairman designate of the proposed new regulator in 2003, about a year before the HCC officially came into being. The birth of the organisation and the way it was constituted did not entirely meet with his approval:

- Firstly, he was not informed that a separate regulator was to be created to regulate FTs. This went contrary to the recommendations in the Bristol Inquiry report that all forms of systems regulation should be under the umbrella of one entity and that lines of responsibility should be clear, avoiding duplications and gaps.[25]
- Secondly, he found that he was presented with standards, formulated by the DH with which he was not content.[26]
- Thirdly, he found that the HCC was to be tasked with handling second-tier complaints,[27] whereas, as could be seen from the Bristol report, he considered it very important that the healthcare regulator had its focus on safety and quality standards. Accordingly, he did not consider that the HCC was an appropriate place to lodge responsibility for complaints handling – an activity which, as will be seen, came to occupy a great deal of the organisation's resources and attention.

The creation of Monitor

9.24 Professor Kennedy did not hear about the proposal to create an entirely new regulator, Monitor, until an advanced stage had been reached in the preparation of the relevant legislation. His impression was that the officials dealing with the creation of the HCC and

21 Health and Social Care (Community Health and Standards) Act 2003, section 132
22 Health and Social Care (Community Health and Standards) Act 2003, section 46
23 Kennedy WS0000025846, paras 42–43
24 Kennedy WS0000025877, para 152
25 Kennedy WS0000025848, para 47
26 Kennedy WS0000025855, para 74
27 Kennedy WS0000025845, para 35

those developing the Monitor proposals had been acting independently and without communicating with each other.[28] This proposal, he believed, went directly against the recommendation in his Bristol report that there should be one organisational regulator to ensure clarity of roles and responsibilities:

> *... it didn't fit in with the notion that there should be bringing together of bodies so that you didn't have a confusion of responsibility or even the need to negotiate varying responsibilities with the constant tensions that that might provoke. So that one body could be seized with the job and get on with it.*[29]

9.25 While he did not approve of this new development, he decided he had a choice either to work with the reality of it on the basis that it was for elected politicians to decide what should be done, or to walk away from the process. He chose the former course and resolved to do his best in the circumstances.[30]

The formulation of the core standards

9.26 As noted above, Sir Ian claimed to the Inquiry that the national standards had been handed down as if "tablets of stone". By this, he meant that the DH made it clear that it would not be willing to change them until a considerable period of time, such as five years, had elapsed.[31]

9.27 Marcia Fry, Head of Operational Development, Investigations and Complaints at the HCC told the Inquiry that HCC staff had been involved in the preparation of the standards and there had been a form of focus group used.[32] The initially announced core standards were said in the public consultation required by the Act to have been proposed following consultation with patients, professionals and managers. The consultation document was published in February 2004[33] and was subject to a 12-week consultation period, during which a number of public seminars were conducted. Professor Kennedy was listed as a respondent to the consultation.[34]

28 Kennedy WS0000025847, para 45
29 Kennedy T77.48
30 Kennedy WS0000025949, para 47
31 Kennedy WS(2) WS0000075709, para 56. In fact the Standards were amended and re-published in April 2005: Donaldson WS0000070131, para 87
32 Fry T79.171
33 Standards for Better Health: Health Care standards for Services under the NHS (10 February 2004), DH, gateway ref 2604, www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4082339.pdf
34 www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4086841.xls

9.28 The Rt Hon Ben Bradshaw MP, a former Minister for Health, was adamant that the views of the HCC were taken into account and rejected the proposition that it was inappropriate for such standards to be formulated by the DH:

> *... when you say Government, sir, we're talking about a group of people, including medical experts in the Department, the independent chief medical officer and other clinicians, who have chosen to work in the Department, having their input, with input from the regulator. But I think in the end, if you accept the premise of a public national health service ... that is funded by taxpayers, that I think the democratically elected Government or a body, i.e. the Department that is accountable to that Government, has ultimately to have ownership of them. It doesn't mean to say that others shouldn't have input into them, and I think that input happened and was valuable.*[35]

9.29 He felt Ministers had to retain a responsibility for standards:

> *... Ministers have to have the ability to say, "Look, we need to do something about infection. This is* [a] *real issue of public concern and we need to do something about waiting times". And I think to give up that power to an independent body, I mean, the reason that we got infections down so successfully and so quickly, because it was driven politically by Ministers. If we'd left it to an independent body, I'm not sure they would have been so sensitive to the public concern which we were picking up as individual MPs in our surgeries and from ordinary members of the public in our constituencies.*[36]

9.30 He saw the role of the regulator as going beyond the enforcement of minimum standards, to include playing a part in driving improvement.[37]

9.31 Professor Kennedy was not overimpressed by what was produced:

> *The standards were a typical Whitehall set of propositions. They would not frighten too much but were a step in the right direction.*[38]

9.32 Professor David Spiegelhalter, a distinguished statistician who had advised the Bristol Inquiry, told this Inquiry:

> *The HCC had to do their best with rather woolly standards ... I felt that the standards had been put in place with no thought as to how the regulator or trusts would check how they had been met.*[39]

35 Bradshaw T116.16
36 Bradshaw T116.19–20
37 Bradshaw T116.21–22
38 Kennedy WS0000025847, para 42
39 Spiegelhalter WS0000024040, para 15

9.33 Anna Walker, Chief Executive of the HCC, said:

> *The standards laid down for the HCC were produced by the Department of Health and not by clinicians or patients and therefore did not immediately relate to clinicians and their areas of expertise.*[40]

9.34 Marcia Fry, who became the HCC Head of Operational Development in 2004, but assisted Sir Ian from May 2003 in establishing the organisation, said of the standards:

> *My own view is that the standards were drafted in such a way that if met they were unobjectionable and indeed highly desirable. However, in some respects they were a counsel of perfection and a bit too good to be true ... I think it would have been more helpful to trusts and the HCC to have something more specific to base an assessment of quality on.*[41]

9.35 In her oral evidence, which benefited from her perspective gained from having worked in the DH on the policy which led to the Act creating the HCC, she explained how the standards came to be in the form they took and expressed her lack of enthusiasm for them. She said that the original intention had been to have detailed, auditable standards, as adopted in some other countries, but that, following the recommendations of the Better Regulation Taskforce and the perceived need to reduce the bureaucratic burden on organisations:

> *... the emphasis was on reducing the burden of regulation, and so something less prescriptive, less detailed was required. And so the standards became ... almost an embodiment of the principles of clinical governance, which are absolutely right and fine, but because of the way they're written, some are at different levels, some are very broad, they're very difficult to assess against in any detailed way. And I think those who write in academic circles about standards would say that you needed to devise standards and an assessment method together, because it depends what you're looking for, how you look for it, which is why you end up with something very much more detailed for the hygiene code, which is looking for very specific things, than something broader where you're trying to understand systems of governance and assurance.*[42]

9.36 Robert Cleary, the former Head of Standards Based Assessments at the HCC, took the view that the standards did not reflect the recommendations in the Bristol report, which envisaged that they should be produced by a process which engaged clinicians in their creation. In his view, a 12-week statutory consultation exercise did not achieve this. However, he thought that

40 A Walker WS0000028546, para 27(d)
41 Fry WS0000026568, para 8
42 Fry T79.170–171

getting standards of a generic, high-level nature, created by front-line clinicians would have been difficult and, perhaps, impracticable.[43]

9.37 It is clear that both Professor Kennedy and other HCC officials attempted to have the standards changed before they were published. At the request of the relevant DH Minister at the time, Lord Warner,[44] the DH shared a draft of the standards with Professor Kennedy in January 2004. At this point, the HCC was still a "shadow" organisation and, as Professor Kennedy pointed out,[45] its skeleton staff were preoccupied with setting up the organisation itself. In any event, Sir Ian was recorded as suggesting a few minor drafting amendments and that, following subsequent discussions, the HCC was "happy" with the current draft.[46]

9.38 The HCC came into formal existence on 1 April 2004, at which point the standards, which were essential to its ability to fulfil its statutory task, had not been published. In a letter of 26 May 2004 to Lord Warner, Professor Kennedy made detailed comments, on behalf of his fellow commissioners, to the DH as part of the consultation process. As noted above, Professor Kennedy was listed as a respondent to the public consultation. His observations included the following:[47]

- The wording of some standards was too specific and detailed, running the danger of stifling improvement initiatives.
- Many standards referred:

 To having "systems in place". The issue is not whether an organisation has systems in place but whether they are actually doing something in the area in question. For example healthcare organisations should not just have systems in place to ensure that the risk of infections to patients, staff and visitors is minimised; they should ensure that these risks are minimised. Our job will then be to draw up criteria which can check this.

- He endorsed an approach whereby the core standards were minimum standards to be universally observed, while the developmental standards were intended to provide scope for improvement at different paces and levels in different organisations.
- There was a need to allow for adjustment of the standards in light of experience. He suggested that there ought to be a mechanism to allow for this.
- If the standards were too complex, then the same would apply to the criteria for measuring compliance and it would be difficult to reduce the regulatory burden.

43 Cleary T95.31–32
44 LD/11 WS0000070678
45 Kennedy WS(2) WS0000075706, para 45
46 LD/12 WS0000070682
47 LD/15 WS0000070737–40

- He pointed out what were felt to be omissions from the standards:
 - There was a lack of sufficient reflection in every standard of the need to focus on patients and the public.
 - The "governance" domain did not encompass all areas of good governance and, further, "Wording in this set of standards in particular relies too much on the concern of having systems in place rather than achieving things".
 - Safety standards needed to capture "near misses" as well as actual incidents.

9.39 In Professor Kennedy's view, most of the issues raised, particularly those relating to the governance standard, were not accepted by the DH in the final published version of the standards.[48]

9.40 Following up on this letter, Anna Walker, while expressing strong support for the Government's approach to standards, wrote to the DH with a suggested revision of the draft:[49]

- She expressed concern at the apparent mixture of standards with criteria for assessment and the level of detail, which ran a danger of leading the HCC into increasing detail in its assessments.
- She suggested that a simplification of the standards would allow an annual assessment based on standards, both core and developmental, national and local targets, and an assessment of corporate leadership.
- By way of example she suggested a standard that: "Health care organisations provide care, treatment and services according to nationally agreed evidence based best practice,"[50] which would be assessed against criteria, including that:
 - *The organisation is maintaining and developing an evidence base that included NICE, NSFs* [National Service Frameworks] *and agreed national guidance*
 - *Staff are informed about the evidence base and use it*
 - *The organisation has a mechanism for monitoring its use in practice.*

9.41 In a reply in June 2004, Professor Sir Liam Donaldson, Chief Medical Officer at the time, stated that the DH regarded the standards as an integral part of the performance regime and were to set minimum standards for FTs.[51] He expressed the view that it was for the DH to define the baseline acceptable level of care to be provided throughout the NHS in England.
He concluded that the HCC's model failed to achieve the DH's criteria for a number of reasons, including:[52]

48 Kennedy WS(2) WS0000075707, para 48
49 LD/16 WS0000070743
50 LD/16 WS0000070748
51 LD/17 WS0000070752
52 LD/17 WS0000070752–753

- It went against the theme identified from the responses that the standards were too high level rather than too detailed;
- The distinction between core and developmental standards was regarded as helpful;
- An integrated performance regime would not function as desired if there were no such distinction;
- There was a need to define baseline performance for FTs;
- Primary Care Trusts (PCT) needed to be able to determine if baseline levels had been met;
- The model proposed by the HCC strayed substantially from the model consulted on.

9.42 However, he accepted that the relationship between core and developmental standards required better explanation: "The core standards are intended to represent the baseline level of achievement in areas set out by the developmental standards."

9.43 He also accepted that standards with a "process focus" were "not ideal" and that a revision of some would focus on outcomes.

9.44 On 5 July 2004, Lord Warner, via his private secretary, indicated by email that he did not accept a revised draft that had been offered for his consideration by DH officials. His comments included the following:[53]

- A perceived need to separate the core standards from the developmental, making it clear that the core standards were mandatory;
- He wanted to know why five additional core standards and 12 more developmental standards had appeared;
- He rejected the HCC approach and felt a degree of process was inevitable in standards, as: "you cannot have good outcomes without good process".

9.45 Lord Warner stated that the HCC would have to fit in with the standards, which had to have meaning.

9.46 On 12 July, the Secretary of State for Health at the time, the Rt Hon John Reid MP (now Lord Reid), gave his approval to the standards, subject to some relatively minor amendments.[54]

9.47 On 16 July, presumably in response to a draft produced following the internal DH discussion described above, Professor Kennedy wrote again,[55] commenting in detail on the draft. Among the comments was one suggestion that there should be clarification that:

53 LD/18 WS0000070756–757
54 LD/19 WS0000070761
55 LD/21 WS0000070766

Where core standards lay down requirements in the language of process and systems, the Healthcare Commission will (over time) assess outcomes and performance as a result of having those processes and systems in place.

9.48 He also warned that the draft gave a hostage to fortune in a statement that: "Core standards also serve to assure the public that all services, wherever provided, will be safe and of an acceptable quality."

9.49 He urged that this sentence be deleted because: "The word 'assurance' may be too strong; aberrant but as yet undetected behaviour may be taking place."

9.50 In his evidence to the Inquiry, he noted that the sentence to which he objected was retained in the standards published later in the same month.[56]

9.51 Sir Liam told the Inquiry he had shared Professor Kennedy's disappointment at the treatment of the developmental standards, which, according to the latter, were "effectively shelved".[57] He pointed out to the Inquiry that the final decision with regard to the approach and language of the standards rested with Ministers and the Government, but that the process in reaching that point included regard being given to the views of the HCC, although not all its suggestions were accepted.[58]

9.52 Professor Kennedy said that he had been keen to engage clinicians in the process of formulating the standards and to identify what they, as experts, considered as critical. However, the complexities of aligning the various policies meant, he thought, that: "Simple notions at the heart of regulation got lost."[59]

9.53 Marcia Fry told the Inquiry:

I think the problem is there's such a strange dichotomy of views about what standards are and what level of detail and what's effective and what's not, that after going round the houses so many times and trying to input into the debate, you came to a point we had to accept what was given.[60]

9.54 Professor Kennedy did not consider that the standards handed to the HCC were what he had envisaged in the recommendations of the Bristol Inquiry:

56 Kennedy WS(2) WS0000075709, para 58.2
57 Kennedy WS0000025847, para 43; Donaldson WS0000070129, paras 81–82
58 Donaldson WS00000701031, para 88
59 Kennedy WS(2) WS0000075709, para 57
60 Fry T79.172

... was the Healthcare Commission able to, as it were, set down the standards which were thought to be appropriate for the delivery of good care for patients, having consulted patients and professionals who look after them? The answer is no, the Healthcare Commission wasn't able to do that, because the standards were handed down from Government.[61]

9.55 Anna Walker said that the standards did not appear relevant to clinicians:

... the standards laid down for the HCC were produced by the Department of Health and not by clinicians or patients and therefore did not immediately relate to clinicians and their areas of expertise.[62]

9.56 Martin Bardsley, who was Head of Screening and Surveillance at the HCC, thought that the standards were difficult to assess:

I think the standards, contained a lot of aspiration and a lot of hopes about what constituted a good quality healthcare service in that sense. I don't know if that makes them unrealistic. It certainly made them quite difficult to assess.[63]

The involvement of the Healthcare Commission in second-tier complaints

9.57 There had been evidence available to the DH since at least 2001 that the complaints system then being operated was unsatisfactory. In March 2001, the DH published a report which revealed that only 25% of complainants who went on to the then available second tier believed their complaints had been handled satisfactorily. It recommended the introduction of a uniform national procedure with clear criteria for reviews. It was also recommended that a properly resourced system of local complaints handling, for which NHS boards were to be accountable, was required, together with a truly independent and effective second stage.[64]

9.58 In April 2003, the DH proposed a new procedure in which the function of reviewing complaints would be placed with the HCC when formed.[65]

61 Kennedy T77.30
62 A Walker WS0000028546, para 27(d)
63 Bardsley T82.36
64 MF/1 WS0000026599, *NHS Complaints Procedure: National evaluation*
65 MF/5 WS0000026797, *NHS Complaints Reform: Making things right*

9.59 This proposal was vigorously opposed by Professor Kennedy. He told the Inquiry:

> *I can remember pleading that dealing with complaints should not be within the remit of the regulator. I thought it was a good idea for regulators to receive information about complaints but not to adjudicate upon them. I thought this would be hugely onerous and it would remove the incentive for Trusts to resolve complaints themselves.*[66]

9.60 Marcia Fry, who, before joining the HCC had worked in the DH in various health policy roles, including the development of the legislation to create the HCC, told the Inquiry:

> *... there'd been a range of discussions about how the second stage should be handled, and a number of bodies were put forward for this role, and I don't think anybody thought that they wanted it, basically ...*
>
> *... I honestly think the Department of Health didn't know where else to put it. My view, in retrospect, is that a second stage run from the national level is actually misguided.*[67]

9.61 She thought, in retrospect, that this had been a misguided move because the HCC was too remote to effect local resolutions, and also because of the bureaucratic burden it imposed on the HCC.

9.62 Having transferred responsibility to the HCC, the DH announced a pause in implementing the reform of the local level of the system, to allow for consideration of the recommendations of the Shipman Inquiry. This process of change to the new system was heavily criticised by the Health Service Ombudsman in her report published in March 2005.[68] She wrote:

> *The pattern in moving towards a new procedure seems to have been one of 'slippage and scramble'. The slippage is exemplified both by the time between the end of the listening exercise in October 2001 and the issue of* Making Things Right *over 18 months later in April 2003, and by the delay from intended full implementation in April 2004 to partial implementation at the end of July 2004. More changes are promised in 2005. The scramble is exemplified by the six week listening exercise in 2001 ... and the rushed finalisation of regulations for the Healthcare Commission's new role in July 2004. Such long periods of comparative inactivity, interspersed with much shorter periods of frantic activity to unrealistic deadlines, is not conducive to well planned and thought through change.*[69]

66 Kennedy WS0000025845, para 36
67 Fry T79.111–112
68 Making Things Better?: A report on reform of the NHS complaints procedure in England (March 2005), The Stationery Office HC413, p16, para 84. For a fuller history of the process of reform see Annex A to the Ombudsman's report (p23)
69 Making Things Better?: A Report on reform of the NHS complaints procedure in England (March 2005), The Stationery Office HC413, p16, para 84

The Healthcare Commission's vision

9.63 In 2004, the HCC published a document, *Our Vision for the Commission of Healthcare Audit and Inspection*,[70] setting out its approach to its functions. In summary, the HCC's principal aims were:[71]

- Promoting improvement in the provision of healthcare through active engagement with providers and recipients of care;
- Reinforcing accountability of organisations to assure themselves of the standards of care commissioned or provided.

 It was the HCC's view that improvement could only come about through the actions of organisations and their boards. In this context, serious consideration was given to whether the HCC should assess the competence of boards, but it was decided this would duplicate the function of Monitor and, in any event, it was an unpopular proposal throughout the NHS;[72]
- Working with patients to define what was important in improving health and healthcare and reporting back to them.

 In pursuit of this aim, the HCC sought new ways of consulting patients, worked with patient representative organisations, conducted patient surveys and offered Patient and Public Involvement Forums (PPIFs) and local Overview and Scrutiny Committees (OSCs) the chance to comment during the Annual Health Check process. A patient engagement group was established within the HCC itself;[73]
- Working with clinicians and clinical bodies to establish benchmarks of good performance and to determine what measures would be of the most assistance in the care and treatment of patients.

 Ms Walker told the Inquiry it was of fundamental importance to the HCC to engage clinicians to identify what they considered to be the most useful measures of clinical practice, and in this way to include in its assessment "bottom up" measures, approved and created by clinicians, as well as "top down" ones required by the Government;[74]
- Emphasising the rights of vulnerable people.

 Ms Walker said that the HCC paid particular attention to the care of the vulnerable, including the elderly;[75]

70 A Walker WS0000028545, para 26
71 A Walker WS0000028545, para 27
72 A Walker WS0000028545, para 27b
73 A Walker WS27c WS0000028545–6, para 27c
74 A Walker WS27c WS0000028546–7, para 27d
75 A Walker WS0000028547, para 27e

- Focusing on what healthcare information said about performance and the risk of poor outcomes for people.

 Ms Walker said that a fundamental premise of the HCC was that there was an abundance of information about the NHS and its performance, but that it was not brought together and systematically analysed:

 Seen in isolation and not subjected to rigorous analysis, any disputes about the quality of care could be, and frequently were, converted into apparently abstract disputes about statistics and the proper interpretation of data (the Trust exemplified this problem). The Healthcare Commission saw it as one of its most important tasks to identify the various sources of information, to bring them together and analyse them so as to produce the "richer picture".[76]

- Making information about quality of care available and accessible to support better informed decisions and reinforce other ways of promoting improvement;[77]
- Ensuring "robust intervention in tackling poor performance".

 The HCC intended to engage with trusts in a variety of ways to secure change where there was poor performance;[78]
- Recognition of the importance of and necessity for visits and inspection.

 These had to be targeted and proportionate, making effective use of all available information, including any generated by CHI;[79]
- Working with other bodies in partnership;[80]
- Establishing local offices to act as the eyes and ears of the HCC and to build up local relationships with patients, clinicians, trusts and other organisations.[81]

The Healthcare Commission and the commissioning process

9.64 The statutory remit of the HCC included the regulation of primary care trusts (PCTs), as these were included in the definition of "NHS bodies". Therefore, it had a responsibility to regulate not only the direct provision of care by PCTs but also their commissioning function. This was not a welcome change in some senior quarters and the performance of this function was not well understood.

76 A Walker WS0000028547, para 27f
77 A Walker WS0000028548, para 27g
78 A Walker WS0000028548, para 27h
79 A Walker WS0000028548, para 27j
80 A Walker WS0000028549, para 27k
81 A Walker WS0000028550, para 27i

9.65 Roger Davidson, the HCC Head of External Affairs, told the Inquiry that Professor Kennedy and Anna Walker had been very keen that there should be an independent assessment of the commissioning process, given that some £80 billion of public funds was spent in this way.[82]

9.66 Ms Walker explained that they had argued strongly from the outset that the HCC should regulate the commissioning function.[83]

9.67 This enthusiasm was not shared at the time by Sir David Nicholson, Chief Executive of the NHS. In May 2008, Professor Kennedy asked him at a meeting whether he was now more at ease with this; Sir David responded that he would never be content with it, but he had now lost the argument twice over. He explained his reasons.[84]

9.68 Firstly, he had an "ideological" objection: to him, the NHS was a system of which the HCC was a part:

> *The job of the system as a whole is to improve services for patients and regulation should be part of that, not separate from it.*

9.69 In response, Professor Kennedy said he agreed that the regulator should be part of the system as a whole, but he also thought there was room for an independent commentary on how well commissioning was going.

9.70 Sir David's second objection was practical. He and Ministers were strongly in favour of localism, but Ministers also wanted to monitor specific issues. He feared that the system would be "overloaded" by regulatory oversight of commissioning and that this would leave less room for the local perspective:

> *Moreover if commissioners had to look to satisfy the regulator's requirement, there would be less room for them to meet the concerns of the NHS Leadership team, Government or patients and he saw this as a problem.*

9.71 Professor Kennedy and Ms Walker asserted that the regulator ought to be able to work with the wishes of NHS leadership, Government and patients.

9.72 His third objection was also practical: he feared attention to commissioning would distract the HCC from the formidable task of regulating the provision of services by GPs.

82 Davidson WS0000035054, para 13
83 A Walker T83.24–25
84 RD/1 WS0000035078–79

9.73 The experience of the South Staffordshire PCT (SSPCT) of regulation by the HCC was described by Yvonne Sawbridge, Director of Quality and Nursing for SSPCT, who saw a difference of approach between the regulation of the PCT in its role as a provider and in its commissioning function:

> *It was muddled, but how it worked in practice, in 06/07, was that your submission was based on your provision. There were three tests. There was very clearly a focus, an emphasis on your provider. So the submission that you put in, your compliance was around you as a provider. And then there was "reasonable assurance around independent contractors", were the words that were used, but with no definition, just saying you had to have some reasonable assurance that your independent contractor services were complying with these standards. And "reasonable steps", I think, were the words that were used around commissioned services, and we interpreted that as understanding they had a process in place, they were submitting their standards, their statutory duty of governance was being delivered by their board and we needed to know that that process had taken place. And we were not assessed on our responsibility as commissioners other than on that basis.*[85]

9.74 In effect, she agreed, "reasonable assurance" for the PCT as a commissioner consisted of the provider's own assessment of compliance. Had more been expected of PCTs, she pointed out, they would have needed to employ more staff to monitor quality.[86]

Assessment process

Star rating system

9.75 The HCC briefly adopted a star rating system for trusts that it had inherited from CHI, under which three stars represented the highest possible rating. This was a temporary measure while the HCC set up its own system of assessing trusts against the core standards.

9.76 The Trust had achieved a three-star rating in spite of a highly critical CHI clinical governance review in 2002.[87] In 2004 the HCC re-rated the Trust at zero stars, largely, it appears, because of its failure to submit the required data.

85 Sawbridge T64.13
86 Sawbridge T64.14
87 HCC0016000108, *Mid Staffordshire General Hospitals Trust – Clinical Governance Review* (Jan 2002), Commission for Health Improvement. For a description of the report on the Trust see *Chapter 1: Warning signs*

The Healthcare Commission's approach to assessment

Vision

9.77 As already noted, the HCC was obliged to undertake annually a review of each NHS organisation under its jurisdiction. In a document setting out the HCC's vision, the HCC listed what such an assessment had to cover:

> *... the assessment must address three central matters: the quality of care received by patients; the quality of the patient's experience, particularly along the pathway between organisations and services; and the quality of organisations and their capacity to produce improvements in service.*[88]

9.78 In order to undertake assessments proportionately the HCC intended to:

- Make more effective use of information;
- Act in a partnership with patients and organisations;
- Establish and use a local presence;
- Continue to use inspections but develop techniques of assessment reducing the need for routine visits. It would continue to undertake visits but they would be carefully targeted and generally be "diagnostic", "confirmatory" or "facilitative".

The reality

9.79 Whatever the intention of the DH in setting the core standards against which the HCC assessment would be conducted, the HCC officials felt they were confronting a culture which would not automatically embrace their spirit. Thus Robert Cleary told the Inquiry:

> *I think there probably was quite a widespread attitude to the assessment that it was a process that you needed to get through, that you needed to get as good a result as possible, that wasn't universal. But I think many organisations treated it in that way. I don't think that automatically translates into a more general attitude towards minimum standards or an understanding of the importance of providing good outcomes.*[89]

9.80 He felt that at least some of the standards, by focusing on processes not outcomes, could encourage in those imbued with such a culture an attitude of "lip service" and "box ticking".[90]

9.81 Marcia Fry gave evidence to the same effect. She pointed to the example of core standard C14, which required organisations to have "systems in place to ensure" patients and carers had suitable information about complaints procedures, and so on. In 2005/06, she said, only 22

88 AW/5 WS0000028898, para 4
89 Cleary T95.29
90 Cleary T95.27–28

out of 570 trusts declared non-compliance with this standard. The implication she drew was that other trusts may have been adopting a literal approach, rather than accepting the spirit of the standard and examining whether their systems were effective:

> *To me this begs the question about the mentality and culture of the people working in the NHS. They know what the standard is attempting to assess, and yet would rather adopt a literal interpretation of the words. The boxes are ticked as compliant when many trusts knew that actually they were poor in this regard.*[91]

Assessment method

9.82 The purpose of the assessment conducted by the HCC was to produce a score in two parts: quality of service and use of resources. The idea was to combine an assessment of compliance against core standards and national targets, and use of resources into these scores.[92] Additionally, information from service reviews and performance against new national targets was meant to inform an assessment of what progress was being made developmentally, but this aspect was not focused upon before the abolition of the HCC. Acute trusts were assessed in relation to core standards, national targets, new national targets and acute hospital reviews. In 2006/07 these reviews were on management of admissions, management of medicine and diagnostic services, and children's services.

9.83 In relation to compliance with standards and national targets, a four-point scale was used: "fully met", "almost met", "partly met" and "not met". New national targets, improvement reviews and the acute hospital reviews were also scored on a four-point scale, but this consisted of "excellent", "good", "fair" and "weak". The results for each trust were published, as was the HCC's assessment of the answers to six questions:

> *How long will I wait?*
>
> *How safe and clean is it?*
>
> *How good is the care I receive?*
>
> *Will I be treated with dignity and respect?*
>
> *Does the organisation help me stay healthy?*
>
> *How well is the organisation managed?*[93]

9.84 Considerable emphasis was placed on the self-declaration of trusts, but there were in fact a number of streams of information feeding into the assessment undertaken by the HCC. The process adopted was, in summary, as follows:

91 Fry WS0000026590, para 96
92 IK/5 WS0000026110, *The Annual Health Check: Assessing and rating the NHS* (October 2006), page 3
93 IK/5 WS0000026114, *The Annual Health Check: Assessing and rating the NHS* (October 2006), page 7

9.85 *Trust declaration*: Each trust was required to make a declaration in relation to each core standard of compliance or non-compliance. The declaration for each core standard only required a simple "compliance" or "non-compliance"; there was no room for any other comment from the board. All members of the board, including non-executive directors (NEDs), were recommended to sign off on the declaration, although this was not always the case. There was also room for comments from the local OSC(s) as well as others, such as the local SHA and PCT.

9.86 *Comments from other organisations*: Trusts were required to obtain the comments of local organisations, such as commissioners and OSCs, on their draft declarations and these had to be published unedited. Marcia Fry considered that, at least initially, these were of limited assistance as organisations were encouraged to make only high-level comments rather than condescend to particular complaints and incidents.[94]

9.87 *Cross-checking against HCC information*:[95] Declarations were cross-checked by the HCC against an increasing number of items of information held in its database. These included quantitative indicators, which were scored to show a trust's relative position against a national average. There were also qualitative indicators derived from the HCC's own engagement forms and third-party comments on trust declarations. Information was weighted for importance.[96]

9.88 For 2005/06 over 605 indicators were available for cross-checking purposes. These included the CHI audit of child protection and various mortality indicators from 2004/05. The CHI clinical governance review findings were excluded in response to criticism that the information was too old to be relevant.[97] The distribution of items relevant to particular standards was uneven.

9.89 For 2006/07 the HCC had over 1,267 items of information derived from over 60 sources.[98]

9.90 *Statistical analysis*: The data received in relation to each trust was transmitted to the informatics team who subjected it to complex statistical analysis. This was used to calculate a risk that a trust which had declared compliance was not in fact compliant. A list was prepared of the top 10% highest risk trusts – measured by the number of core standards marked as at highest risk of undeclared non-compliance.[99]

9.91 *Selection for a Core Standards Assessment* (CSA): The trusts identified as being in the highest 10% band for risk of undeclared non-compliance would be visited for a CSA. A further 10% of

94 Fry WS0000026568, para 10
95 Hawkins WS0000026335, para 9
96 Bardsley WS0000025220, paras 30–34
97 Bardsley WS0000025223, para 42
98 Bardsley WS0000025224, para 44; MB/8 WS0000025550
99 Bardsley WS0000025221, para 35

trusts would be selected at random. Thus, in theory one in five of trusts were inspected each year. The justifications for this selective approach were:[100]

- Resources;
- The need for any one inspection to be of sufficient intensity to be effective;
- The level of inspection experienced by an organisation should reflect the risk that its quality of care was unacceptably low;
- Honesty and openness were to be incentivised by the risk inspection of any core standard;
- The prevalent concept of "light touch" regulation fostered by the Hampton review on regulatory inspections and enforcements and the work of the Government's Better Regulation Taskforce.[101]

9.92 *Visit by assessors for CSA:* At such visits inspections did not entail an assessment of compliance with all core standards, but with a selection of five of them, based on those where the risk of non-compliance was thought to be greatest. Where non-compliance was found, the scope of the inspection could be broadened. Trusts found to have wrongly declared compliance with standards would be penalised in their "score". It appears that the examination focused on the systems in place rather than the outcomes in relation to the actual standard of care. Shelagh Hawkins, a former Senior Assessment Manager for the HCC, commented that her reports were often edited during the quality assurance process as she felt they were considered "too clinically probing".[102]

9.93 An inspection did not necessarily mean a physical inspection of premises, patients, staff or any service, but could be confined to an inspection of paperwork designed to see if the trust had a system in place to monitor the relevant aspect of compliance, and whether that system had produced sufficient evidence of compliance to support its declaration.[103] Thus, the inspection would often depend on the paper record being an accurate account of what was actually happening on the ground. As Mr Cleary described it:[104]

> *For example, if compliance with training standards was inspected, inspectors would expect to see evidence such as a programme of training and a list of attendees at the training sessions. The inspectors would not go so far as to talk to the nurses who attended the course to check that the training was satisfactory or that it was completed. However, they would need to understand how those responsible for ensuring staff were trained knew that the training was to an acceptable standard and that the staff completed the course ... The inspectors would concentrate on demonstrable paperwork.*

100 Cleary WS0000043522, para 8
101 *Reducing Administrative Burdens: Effective inspection and enforcement* (16 March 2005), Philip Hampton, HM Treasury, http://webarchive.nationalarchives.gov.uk/+/www.hm-treasury.gov.uk/media/7/F/bud05hamptonv1.pdf
102 Hawkins WS0000026336, para 12
103 Cleary WS0000043525, para 15
104 Cleary WS0000043525, para 16

9.94 The HCC developed "prompts" or points it suggested boards should consider in order to inform themselves whether they were compliant with the standards.[105] These were dropped following concerns expressed by management that these 472 prompts would become targets and be over-burdensome to comply with, even though it might be thought that many of them were activities a Trust Board might have been expected to do in any event in some shape or form.[106]

9.95 The assessment produced by the AHC process was not intended to be the end of the HCC's monitoring of the standards of service. Where particular areas of general concern were identified it could and did conduct topic-based reviews. Its work in this regard included topics such as infection control, maternity services and dignity in care.

9.96 In addition, as happened in the case of the Trust, the HCC could conduct formal investigations, carried out by its centrally based investigations team. This method is considered in more detail below.

The process in practice

9.97 In a retrospective review published in 2009,[107] figures were given from the number of trusts whose self-assessments had been higher than the assessment of the HCC on review:

2005/06 The ratings of 55 trusts, not far off 10% of the total number of 570, were downgraded as a result of visits;

2006/07 17 trusts' declarations were subject to qualification following 85 visits by way of inspection. Four of the 17 had been the subject of a random, as opposed to a targeted, inspection.[108]

9.98 This suggests that a significant proportion of trusts at the time were declaring a higher level of compliance than was justified.

9.99 The process of self-declaration was onerous, in that a considerable quantity of evidence had to be collected, and this could still be disconnected from the reality on the ground. An example came from the evidence of SSPCT which was judged non-compliant with certain standards in connection with a hospital (not the Trust) because it was unable to produce the required paperwork, even though the HCC representatives had been taken to see that the relevant hospital had been rebuilt in compliance with the standard.[109] Ironically, this led to the PCT receiving only a "weak" rating for quality of services in 2007, while the Trust was adjudged

105 CURE0005000171, *Assessment for Improvement – Understanding the Standards*, page 6; Cleary T95.38–39
106 TD/5 WS0001000352, *Criteria for assessing core standards* (HCC); Cleary T95.42–43, 50–52
107 RC/3 WS0000043608, page 34
108 Cleary T95.83–84
109 Sawbridge WS0000013402, para 45

to have complied. The evidence, or a list of evidence, on which the declaration was based did not have to be sent in with the declaration, but had to be available if an inspection took place.[110]

9.100 Una O'Brien, now Permanent Secretary at the DH, drew on her experience as a senior manager at University College London Hospitals NHS Foundation Trust (UCLH) in preparing for it its first AHC declaration and recalled being tested closely by the Board which required rigorous justification of it: "there was nothing 'light touch' in that approach".[111]

Views on the process

9.101 A survey of 220 trusts of their evaluation of the second year of the AHC (2006/07) produced a broadly favourable response:

- 70% thought the self-declaration was a good use of staff time;
- 93% thought it had a positive impact on patient care, such as through staff awareness;
- 67% thought it had improved patient safety;
- 89% thought it had a positive impact and built on evidence that trusts ought to be gathering in any event.[112]

9.102 These complimentary responses from management need to be measured against the less reassuring view expressed by Dr Val Suarez, then Medical Director at the Trust:

> *... you had the feeling that if you could demonstrate that you had a process in place that was enough to be compliant, even if the process was not necessarily effective.*[113]

9.103 However, she claimed she would never have supported an inaccurate declaration of compliance and never felt under pressure to just tick the box.[114]

9.104 In October 2008, in an email chain involving Dr Heather Wood, who was at the time leading the HCC's investigation into the Trust; Professor David Haslam, National Clinical Adviser to the HCC; and Nick Bishop, a medical adviser to the HCC, highly critical views were expressed about the Annual Health Check process and the claims for it being made by the HCC.[115] The context of the views expressed was that it took place while the investigation into the Trust was continuing and at a time when the HCC was preparing to transfer its responsibilities to the CQC. The email speaks to defects not only in the system but also to the culture in which it operated. The chain was started by Dr Wood, who said she was writing because she was

110 Cleary T95.62; HCC0050000188, *Guidance for Trusts* (2006/7), page 4, "Reasonable assurance is based on documentary evidence that can stand up to internal and external challenge".
111 O'Brien WS0000059320, para 42
112 RC/3 WS0000043585
113 Suarez WS0000012496, para 74
114 Suarez WS0000012496, para 76
115 HCC0000000186–189, Email chain between Heather Wood, David Haslam and Nick Bishop (29 October 2008)

increasingly uncomfortable with claims being made about the AHC that she felt were potentially misleading. She said: "I am writing confidentially because criticising the AHC is an unpopular step and because Mid Staffs is as yet unpublished."

9.105 She said she was aware of HCC staff who reported the AHC as a "paper based tick box exercise" and that it did not achieve what the HCC claimed, in particular that it assisted in the making of informed decisions about care. She went on:

> *Actual information about mortality for example is drowned out by bureaucratic information around assurance processes etc. For example at Mid Staffs our assessment is recorded as 9 out of 9 for standards of care despite this being a trust with very high mortality rates for emergency admissions, an appalling performance in the 2007 inpatient survey and our complaints records show them as having high numbers of unresolved complaints. But for the investigation this rating would stand unchallenged.*

9.106 She ended by saying, "I feel I have to share it as a matter of conscience [...] I have no time and no seniority or clout to do it myself."

9.107 Nick Bishop responded that he thought that some of Dr Wood's concerns were justified but was unclear how this could be pursued so close to the end of the life of the HCC and at a time when what he called "genuine measures of quality", supported by Lord Darzi (then a junior health Minister) and Professor Sir Bruce Keogh (NHS Medical Director), were being developed.

9.108 Professor Haslam replied the following day to say he was "hugely sympathetic" with Dr Wood's views. He said he had discussed the issues off the record with Cynthia Bower (by this time shadow Chief Executive of the CQC). To him:

> *... on the whole, the AHC is meaningless to clinicians. Those in Primary Care don't use it, and those in secondary care don't recognise it ... it isn't seen to measure the things that really matter to clinicians and their patients, partly because of overt gaming and partly because few clinicians actually identify personally with their trust anyway – they identify more with their service and their specialty.*

9.109 He agreed with Mr Bishop that there was not much that could be done at the HCC during its remaining life and feared in any event that some (unidentified) senior members of the HCC would not understand the point.

9.110 Dr Wood maintained the views she expressed in the email in her evidence to the Inquiry. In particular, while stressing that the assessment of core standards was not the only component of the AHC, she had been very uncomfortable with the concept of "quality of care" used in the assessment:

Now, whatever way you look at it, I am sure that for the majority of us quality of care means what happens to patients in terms of their diagnosis and their treatment and the outcome for them. And I felt very uncomfortable that a whole lot of information, which I know was checked this way and that way and the other way and so on, was fed into a machine, but what came out was not a measure of what patients experienced, because so many of the standards didn't relate to patient care.[116]

... Perhaps if the element of it that was labelled "quality of care" had been called something like, I don't know, "organisational arrangements" or something, because there's no doubt that many – probably all of the standards that were included were important things for trusts to do, whether it's having good relationships with your local authority, or effective waste disposal and so on. So you wouldn't quibble with them as being things that trusts should do, but it was the use of the word "quality of care".[117]

9.111 She explained that she had understood criticism of the AHC to be unpopular with the senior echelons of the HCC because it was such a large component of what the HCC did in terms of the time and resources invested in it.[118] She accepted in hindsight that she had not appreciated that the HCC had been given very little flexibility in the standards it was handed by the Government.

9.112 She told the Inquiry that she thought that the standards, and the way they were phrased, led to a legalistic approach at the HCC, which emphasised the procedural over the outcomes of process:

I think the approach to core standards became overly legalistic ... in that I think the Commission's legal advisers took a stance that everything had to be done in exactly the same way for every organisation. Reasonable enough, but there were these sort of constraints about what was evidence of being compliant, and a lot of it was about assurance. And I'm afraid I'm going to put assurance in the same category as action plans in some ways. But if the organisation could demonstrate that it had, for example, a risk management committee and then show that minutes of that went up, perhaps, to the audit committee or whatever is above that, and in due course perhaps was attached to the agenda for the board, because often they would not actually really be considered, then I think technically our assessors may have had to concede that the system was there. I think that's what was one of the problems ... even after the Mid Staffs report, they still got a high mark for privacy and dignity, because they had whatever it was, a policy, a person who was supposed to look after it.[119]

116 Wood T81.38
117 Wood T81.44–45
118 Wood T81.41
119 Wood T81.50–51

9.113 She suggested that the culture of the NHS led to senior managers giving "clear" answers in declarations designed to minimise the chance of further scrutiny. She had concluded that self-assessment was not a realistic basis for a regulatory system.[120]

9.114 She was not prepared to criticise the assessment teams who undertook risk-based assessments, one of which, as will be seen below, failed to detect any non-compliance on the Trust's part in mid 2007. She was clear that the system in which they worked was too constrained:

> *I think that regional staff were constrained as to what they could do. I don't think they were allowed, really, to put any degree of rigorous scrutiny, providing that the trust was able to supply really the documentation. So I hesitate to criticise my regional colleagues, because I have had some say to me, "It is a most frustrating process".*[121]

9.115 However, she formed the view, as a result of the investigation she led in 2007, that the Trust had been in "chaos" at the time of the assessment.[122]

9.116 Among the other criticisms about the AHC she expressed to the Inquiry were:

- There was pressure on the HCC to show there was year-on-year improvement;[123]
- It was intended to be a snapshot of measurement against prescribed standards, not a means of identifying failing trusts;[124]
- Important matters relevant to quality of care, such as the adequacy of clinical staffing, often did not form part of the standards;[125]
- The measure of some standards did not refer directly to the standard of care, even if the standard itself did. For example, privacy and dignity was measured by reference to whether appropriate policies were in place, rather than whether the required level of privacy and dignity was actually delivered;[126]
- She considered that the AHC did not give sufficient weight to the results of national patient and staff surveys.[127]

9.117 Martin Bardsley thought that the nature of the standards made them difficult to assess, as many of them were, he thought, aspirational.[128] He pointed out that the AHC was known not to be wholly effective at identifying problems and that the HCC relied on other methods:

120 Wood WS0000025032, para 18; T81.51–52
121 Wood T81.78–79
122 HCC0000000174, Notes of meeting on Investigation into MS NHS FT (1 July 2008); Wood T81.80
123 Wood WS0000025036, para 40
124 Wood WS0000025036, para 41
125 Wood WS0000025039, para 49
126 Wood WS0000025039, para 49
127 Wood WS0000025038, para 47
128 Bardsley T82.36

Q: I'm getting the sense from what you say that perhaps it wasn't the annual health check and the process, of cross-checking that that you thought would be the means of picking up on problems particularly within trusts. It was things like the mortality outliers process that was far more likely to do that.

A. Yes ... I feel that quite strongly, and the annual health check had limitations that we're aware of: its ability to look into these areas, which is why we needed different mechanisms, different ways of using information and different ways of following those up, and the mortality outliers was one example of that process.[129]

9.118 However, he felt that the AHC was useful in bringing together and at least beginning to make sense of a wide range of information about the provision of care, albeit that the overall rating was the tip of an iceberg of many items of information.[130]

9.119 Robert Cleary, the former Head of Standards Based Assessment at the HCC, told the Inquiry that although the standards themselves were fixed, it had been for the HCC to establish criteria by which they could be assessed.[131] In detailed evidence about how the assessment process worked he identified a number of issues:

- There was a shortage of useable outcome measures.
- In many areas there was a lack of reliable, centrally maintained data.
- Even where the information was available, it could be difficult to identify a threshold of acceptability. In part, he suggested, this was because of the DH's reluctance to agree to a criterion that might be understood as a target.
- The HCC expected trusts to demonstrate not only that they had a clinical governance system but to show what evidence had actually flowed through the system. However, it was possible for boards and therefore the HCC to be misled by selection of examples where the system could be said to have worked, which were in fact unrepresentative. In such circumstances the assessment system relied on information coming from third party sources, which suggested the picture being presented was inaccurate.
- He was not confident that the annual assessment process was capable of assuring the application of quality standards:

 I think the notion of an annual cycle is an odd artificial thing that may be useful in planning, may be useful for managerial purposes, it may be useful for performance management, but in terms of assuring whether decent standards of quality are in place, I don't think – I don't see its role.[132]

129 Bardsley T82.115–116
130 Bardsley T82.119
131 Cleary WS0000043522, para 4
132 Cleary T95.65–70, 81, 76

9.120 However, he thought the system was the best that could be devised to meet the conflicting demands that it be risk based,[133] "light touch"[134] and annually universal.[135]

9.121 Martin Bardsley pointed to the complexity of the process. There were over 20,000 potential breaches of compliance to be checked for against data on the large number of indicators available.[136] This was bound to be challenging, given the need to check 40 standards across 400 to 500 organisations.[137]

9.122 When asked about the Trust's declaration in 2007/08, Anna Walker did not entirely agree that the standards missed the point but did accept that they were open to misleading declarations by trusts:

> *I think that the standards were not ideal, and we've talked about that. Were they describing more processes than the outcomes that were needed? And I can see that. But there was no doubt in the NHS's mind as a whole about what those standards were striving after. How the board came to the judgement it did, that it was compliant, I absolutely struggle to understand.*[138]

9.123 When asked about Dr Wood's views as expressed in the email considered above, she expressed disappointment that these concerns had not been drawn to her attention, as she believed that the HCC was an "open" organisation. She accepted that the AHC did not cover all areas which would have been of concern to patients, although she felt that would have been impossible to achieve.[139] She contended that the HCC could have looked at the suggestion that labelling one part of the rating as "quality of care" was misleading if that concern had been raised with her, which it was not.[140] She said the HCC had recognised that clinicians had not been effectively engaged in the preparation of the standards, and that that had been the reason they had been seeking to persuade professional bodies to push the DH into extending the quality of care elements of the AHC. The DH, she explained, had been reluctant to allow quality measures to be extended further because of the wish to reduce, rather than increase, the regulatory burden.[141]

133 Cleary WS0000043522–3, para 8
134 Cleary WS0000043523, para 8.5
135 Cleary WS0000043530, para 27
136 Bardsley WS0000025219, paras 25–27
137 Bardsley T82.77–80
138 A Walker T83.183
139 A Walker T83.63–64
140 A Walker T83.65
141 A Walker T83.70

Healthcare Commission contacts with the Trust

Complaint about hygiene – March 2006

9.124 In March 2006, Terry Deighton, an erstwhile member of the patients' forum called the HCC to complain about the lack of cleanliness in A&E at the Trust following an inspection by the Patient and Public Involvement Forum (PPIF). Mr Deighton had taken part in the inspection on 23 January 2006 but resigned afterwards, dissatisfied at how the PPIF planned to take it forward.[142] He spoke to Shelagh Hawkins about this and also raised issues about the new Chair of the PPIF, a matter Ms Hawkins rightly did not wish to concern herself with.[143]

9.125 Following this call, Ms Hawkins visited the Trust on 16 March 2006 and raised the issue with Martin Yeates. He suggested she look at A&E for herself and showed her plans for reconfiguring A&E. In A&E, Ms Hawkins observed damaged and blood-stained chairs and damaged walls in the patient and toilet areas. She observed that infection control risks appeared to be high owing to a number of uncleanable surfaces, peeling wallpaper and furniture that could also not be cleaned.

9.126 Mr Yeates acknowledged that repair was currently poor, but that a "full improvement plan" had now been approved by the Board. She was surprised to be told that the seating was to be replaced by identical furniture and recommended to the manager a more effective type of chair.[144]

9.127 Ms Hawkins thereafter attended several PPIF meetings. Therefore, she was aware that it was carrying out monthly visits because of its concern about infection control and wanted to see what was happening on the wards. She thought this was a sensible approach. The reports over time suggested to her less cause for concern about the Trust.[145]

Possible absence of appraisals – April 2006

9.128 On 28 April 2006 Celine Wilkinson, an HCC Assessor, in the course of an inspection of a private hospital noted inconsistencies in the appraisals of doctors who also worked at the Trust. It appeared that the private hospital had written to the Trust requesting confirmation that annual appraisals had been undertaken, but had received no response. A consultant admitted there had been some gaps in NHS annual appraisals.[146] Ms Wilkinson filed an engagement form about this, and Ms Hawkins was made aware of the issue. To Ms Hawkins the absence of evidence of such appraisals suggested they had not been done, but she would have expected that the Shropshire and Staffordshire SHA (predecessor of the West Midlands SHA) would have known whether the appraisals were effective, and based on evidence from a

142 Deighton WS0001000212–3, para 49
143 Deighton WS0001000216, para 63; Hawkins WS0000026343–4, para 37
144 Hawkins WS0000026344, para 38; SH/1 WS0000026368
145 Hawkins WS0000026345, para 40
146 SH/2 WS0000026370

single source like this, she did not feel she could pursue the matter further. She suspected that in many trusts the conduct of appraisals was a box-ticking exercise.[147]

Information about the Trust's complaints procedure – May 2006

9.129 On 12 May 2006 Sharon Llewellyn, the Trust's Complaint Manager, contacted Ms Hawkins. She had just been on a training course on complaints handling and stated that she now realised that the Trust's system needed to improve. The training had highlighted areas of non-compliance against the relevant core standard in the past year and potentially for 2006/07. She said it was now introducing follow-up after investigations.

9.130 Ms Hawkins took no action about this, as complaints were not her responsibility, but she completed an engagement form, which presumably could have been seen by those who were.[148]

9.131 While the late discovery of non-compliance might well have been expected to cause concern, it might also have been taken as an encouraging sign that this information was being volunteered.

Children's services review – 2006

9.132 In mid 2006 the Trust was required to submit data on its children's services as part of the HCC's Children's Service Improvement Review, which was based entirely on submissions made by provider trusts. The Trust failed to return five out of the eight documents required and as a result came in the bottom 10% of the country. This caused Ms Hawkins concern, as it was not a problem other trusts had encountered.[149]

9.133 This failure led to a more formal review process. A meeting between the Trust and the HCC was called to discuss this on 19 May 2006 and was attended by Martin Yeates, Jan Harry (the Trust's Director of Nursing at the time), a nurse from the paediatric department and Shelagh Hawkins. There was a dispute about what the Trust had been asked to complete, but the HCC concern was that without the forms it did not know how good the service being provided was. Ms Hawkins formed the impression that people at the Trust were not good at communicating with each other and that Ms Harry was concerned to find someone to blame. She feared there might be a real problem with clinical governance. Ms Hawkins raised these concerns with her senior management.[150] The Trust was required to complete an appropriate action plan which it opted to have developed at a fully facilitated meeting with the HCC. The HCC representative felt that it had worked effectively with the Trust and that there had been productive engagement between Martin Yeates and the HCC.[151]

147 Hawkins WS0000026346, para 43
148 Hawkins WS0000026346, para 44; SH/3 WS0000026372
149 Hawkins WS0000026347, para 45
150 Hawkins WS0000026347, para 46
151 Hawkins WS0000026348, para 47

9.134 In June 2006 the HCC learnt that the Trust had instructed external auditors to assist it in relation to the review. The auditors contacted HCC; they were recorded as stating that governance arrangements at the Trust were "non-existent", as a result of which they had to contact the HCC on an almost daily basis trying to track down information.[152]

9.135 On 12 June HCC representatives attended an improvement workshop at the Trust at which clinical staff appeared not to have been told that the reason for the weak rating was largely due to the failure of the Trust to submit information to the HCC. However, it was also noted from the documentation that was submitted on training and skills maintenance that this was also weak.[153]

9.136 Ms Hawkins recollected that at or around the time of this meeting she learnt that the Trust lacked sufficient staff qualified in paediatric life support. Indeed she was informed that only one person at the Trust was qualified in this regard. Ms Hawkins was "shocked" at this, because she would have expected at least one qualified person to be on duty on every shift, whenever children were being cared for. Mr Yeates assured her that in spite of this lack of qualification, many staff were trained to an equivalent level and knew how to resuscitate properly. She was told that the necessary training would be arranged[154] and decided no action was justified on this issue as there was no evidence of deaths or serious untoward incidents (SUIs) related to this and the HCC was not the performance manager.[155] She did, however, escalate this to her manager, but given the lack of evidence that the staff lacked the necessary practical skills, nothing was done. Ms Hawkins agreed this meant that the first time it could be shown there was a problem was if something really serious were to happen. She explained:

> *So purely because they hadn't been accredited with a PALS* [paediatric advanced life support] *certificate, it didn't necessarily follow that they weren't delivering good paediatric advanced life support in that trust. So you couldn't necessarily make a leap from there to there. So it needed further explanation – explanation from the trust. And when I asked the trust about this, although I was very assertive with saying, "Well, actually, PALS is what we're looking for here", they assured me that they're getting people on the course. They then came out with an action plan to say this is what they're doing but they actually do have staff who are working at that level who are delivering that care. Now, it would have been awful if a tragedy had happened with a child whilst this happened, but at this point, all I could do in my position was escalate that information upwards.*[156]

152 Hawkins WS0000026349, para 52; SH/7 WS0000026411
153 Hawkins WS0000026350, para 53; SH/8 WS0000026413
154 Hawkins WS0000026350, para 54
155 Hawkins WS0000026350, paras 53–54
156 Hawkins T78.84–85

9.137 An action plan was produced by the Trust later in June.[157] This revealed the extent of the concerns harboured by the HCC in relation to children's services at the Trust. These included:

- Concerns about governance arrangements to ensure accurate and complete submission of information for audit reports;
- A need for a clear definition of responsibilities and accountabilities across the Trust;
- A lack of training in communication with children and young people;
- The lack of life support training already mentioned.

9.138 The formal conclusion of the review, rating the Trust as "weak" for all components of the service except for outpatient services, was published in October 2006.[158]

9.139 On 1 November 2007 Ms Hawkins met the Trust in part to the follow-up on the action plan relating to children's services.[159] This was because although the HCC was not the performance manager, the West Midlands SHA (WMSHA) had not been monitoring this issue. She was assured that the plan was in large part being implemented. At a meeting with the WMSHA on 23 November 2007 the SHA confirmed to the HCC that it had no systems for following up the children's service review.[160]

9.140 She was unaware of the West Midlands peer review of children's services, and therefore of its findings with regard to the insufficiency of staff and their training. She believes she would have delved deeper if she had been aware of it.[161]

Potential non-compliance with the clinical risk management standard – 2006

9.141 On 3 July 2006 Ms Hawkins lodged an engagement form concerning an external audit report commissioned by the Trust that was described as "damning". This indicated that its declaration of compliance with the core standard relating to clinical risk management in the 2005/06 AHC self-declaration was inconsistent with the information now available.[162] Again, at the time Ms Hawkins felt reassured by the actions of the Trust. She believed that it was taking action to sort out its governance problems, including the commissioning of a critical audit report, and noted that Ms Harry had been replaced as Director of Nursing by Dr Helen Moss, about whom Mr Yeates expressed enthusiasm. She also took encouragement from the fact that the Trust had commissioned this audit.[163]

157 SH/9 WS0000026417
158 HCC0000000195, *Improvement Review of Services for Children in Hospital* (Oct 2006), HCC, pages 1–2
159 SH/30 WS0000026545
160 Gordon WS0000024119, para 128
161 Hawkins T78.84
162 SH/10 WS0000026426; Hawkins T78.109
163 Hawkins WS0000026351, para 57

9.142 However, she accepted that, in hindsight, if the subsequent core standards declaration of compliance for 2006/07 was correct then Dr Moss would have had to have been a "miracle worker". Ms Hawkins explained that it was these concerns that in part contributed to the decision to conduct an inspection in July 2007.[164]

Concerns raised about resuscitation equipment – 2006

9.143 On 30 September 2006 further concern was generated by Ms Hawkins and a colleague's inspection of an area of Stafford Hospital that the British Pregnancy Advisory Service (BPAS) was allowed to use one day a week. The rest of the time the area was used by the Trust for NHS work. Several health and safety issues were noted, including oxygen cylinders being left propped up against sinks and other areas to which patients had access, and an absence of risk assessment of patient areas. There was also a resuscitation trolley with old equipment not now to be used, after a change of policy. The nurse present appeared, however, to be aware of this and knew to use a different trolley. There appeared to be considerable confusion in relation to the documentation recording the checking of the resuscitation equipment, and staff were not aware of all the checking processes that were meant to be in place.[165]

9.144 Ms Hawkins thinks she talked to Dr Moss about this, but was assured by her that staff would know which trolley to use. Ms Hawkins felt diffident about pressing the matter because she was engaged on inspecting a BPAS facility which happened to be in an NHS hospital. She did, however, consider her findings indicated "sloppy" governance at the Trust.[166]

Annual Health Check ratings for 2005–2006

9.145 In October 2006 the AHC ratings were published for the year 2005/06. The Trust's rating was Fair/Fair. This did not cause concern in itself, as some trusts were open and honest about compliance, which was encouraged. Ms Hawkins described how these ratings were seen to be of limited value, given that many people felt that they just needed to get used to the system, as this was the first year of the AHC process and it was anticipated that some trusts would hold themselves to a higher standard than others. Additionally, she pointed out that where non-compliance was declared, the HCC was less likely to inspect trusts that were transparent as it did not have the resources to do so in all cases of Fair/Fair ratings.[167]

Health and Safety Executive prosecution

9.146 In November 2006 the HCC became aware that the Health and Safety Executive (HSE) had successfully prosecuted the Trust in respect of the tragic death of a patient who had drowned in a pond at Cannock Hospital in 2003. The area had apparently been identified as a risk for

164 Hawkins T78.112–113
165 Hawkins WS0000026352, para 61; SH/14 WS0000026438
166 Hawkins WS0000026353, para 62
167 Hawkins WS0000026354, para 65

some time but no remedial action had been taken. HSE officers expressed concern about the Trust's risk management procedures and were to undertake a follow-up.[168]

Hygiene Code inspection – January 2007

9.147 On 16 January 2007 Ms Hawkins visited the Trust for a Hygiene Code inspection with Dr Andrea Gordon, an area manager for the HCC. The Code had been published in 2006, but many trusts had declared non-compliance because of lack of resources and because the means of compliance were in development.[169] The HCC conducted a series of "pilot" inspections, one of the first of which was to the Trust. The purpose of the visit was said by HCC witnesses to be to test out the HCC methodology, rather than to constitute a formal inspection of the Trust.[170]

9.148 The Trust management were not entirely clear on the purpose of the visit, which occurred at short notice, but understood, as indicated in a subsequent report to its management board, that it was in part due to the Trust being one of the 41 that had declared non-compliance with the core standard on reduction of healthcare associated infections (HCAIs).[171]

9.149 "Inspection" is something of a misnomer for what the process actually entailed. There was no physical inspection of the premises, but instead documents were looked at and questions were asked of the Trust, the purpose of which was to "assure" the HCC that:

- The action plan for ensuring compliance with the relevant core standard had been effectively implemented;
- The Trust Board had assured itself that it now had effective systems in place to protect patients from HCAIs;
- There were effective arrangements to ensure that the Code was being observed throughout the Trust.[172]

9.150 According to Dr Gordon, this was a fact-finding visit designed to ensure that the Trust was aware of the Code and that the Trust Board was assured it was complying with it.[173]

9.151 Ms Hawkins' summary report (a copy of the full report could not be found), produced in a standard HCC format, recorded her findings that:

- The Trust had "structures in place to ensure the prevention, monitoring and control of HCAI is the responsibility of everyone in the organisation";

168 SH/15 WS0000026440
169 Hawkins WS0000026355, paras 69–71; Gordon WS0000024104, paras 70–76
170 Hawkins WS0000026356, para 72
171 AG/17 WS0000024259
172 Gordon WS0000024106, para 77; SH/18 WS0000026462
173 Gordon WS0000024106, para 79

- Systems had been in place since November 2006 "which now demonstrated that the board has full knowledge of the infection control issues within the Trust";
- Directors had received written information "to assist with their understanding of HCAIs";
- The Board had:

 ... implemented a more robust clinical governance structure to the Trust, which is currently being embedded into the culture of the organisation. The board members interviewed were confident that the new governance arrangements through the organisation would support and assist in the responsibilities that the Board has;

- The Board was aware of the outcomes of the audit and "plans to improve things". The report concluded:

 It is vital that the Healthcare Commission is able to establish that plans have been implemented and that robust reporting systems are in place for infection control within the trust which demonstrate improvement in all areas of infection prevention and control.[174]

9.152 Following the visit, Helen Jenkinson, Infection Control Policy Lead at the HCC, wrote to Mr Yeates following a meeting and praised the Trust on the basis of this report:

I was reassured and indeed impressed with the progress of the management of Healthcare Associated infection and the strategies you have adopted in line with the Code ... since November 2006. Your work towards compliance with the code appears to be on target. We are awaiting the requested documentation in order to complete this process.[175]

9.153 Whatever may have been the intent of the visit, the Trust relied on this letter as evidence of compliance with the core standards in its declaration for the AHC 2006/07 by quoting the letter of Helen Jenkinson.[176]

9.154 Both before and after the inspection, concerns about hygiene were reported by Terry Deighton and Robin Bastin to the HCC. Mr Bastin had been in contact with Ms Jenkinson prior to the report and was surprised by its tone, given the private communications he said he had had with her about *C. difficile* and MRSA. Following the report, he was directed to talk to Lea Pickerill at the HCC and further relayed his concerns about high infection rates at the Trust.[177] Mr Deighton said he made contact with Ms Hawkins and the HCC prior to the report, having first raised the issue of cleanliness with the Trust directly and been unsatisfied with its response, but he felt ultimately that this did no good.[178]

174 SH/18 WS0000026462
175 AG/15 WS0000024253
176 Gordon WS0000024107, para 82; AG/16 WS0000024255
177 Bastin WS0001000007, paras 22–23
178 Deighton WS0001000216, paras 62–63

9.155 However, Ms Hawkins believed the Trust was taking appropriate action.[179] She told the Inquiry:

> *At this point I was aware that there were areas of improvement in respect of infection control necessary at the Trust, but I had been shown plans as to how things would be improved. As far as I could see the Trust was taking appropriate actions. I could not see anything else other than what I reported on the engagement forms. I was however still concerned about governance although I hoped to see improvement as a result of the audits and with Helen Moss taking things forward as promised by Martin Yeates.*

9.156 Ms Hawkins attended a number of PPIF meetings and considered that there was a good level of challenge to the Trust and was "impressed".[180] At one such meeting, on 24 May 2007, she was recorded as having reported that the HCC: "... had undertaken inspections at the trust and were pleased with the improvements at the hospital."[181]

Risk Summit – February 2007

9.157 The HCC developed a system of "risk summits", the purpose of which was to bring together on a local basis regulators who participated in the concordat to discuss the risks posed by trusts.[182] The West Midlands region was the first to start these, under the leadership of Dr Gordon. Invitees included the NHS Litigation Authority (NHSLA), the Commission for Social Care Inspection (CSCI), the Audit Commission, the WMSHA, and the NHS Counter Fraud and Security Management Service.

9.158 The first of these summits occurred on 4 February 2007. At the meeting 21 organisations, including the Trust, were identified as posing some risk.[183] In the case of the Trust the only issues identified were the concerns arising from the HSE prosecution and the issues around the HCC children's service review, both of which have been described above.

Annual Health Care declaration 2006/07

9.159 The Trust's annual declaration for the AHC was submitted to the HCC on 30 April 2007.[184]

9.160 As already noted, the Trust relied on the letter of Helen Jenkinson with regard to its compliance with the Hygiene Code.

179 Hawkins WS0000026357, para 75
180 Hawkins WS0000026345, para 39
181 SH/23 WS0000026493; Hawkins WS0000026358, para 83
182 The concordat was a voluntary agreement between organisations that regulated, audited, inspected or reviewed health and social care in England. It was launched in June 2004 and was led by HCC, which had a statutory responsibility to promote the effective coordination of reviews or assessments relating to the provision of healthcare. See Anna Walker WS0000028575, paras 105–106; IK/3 WS0000026057, page 6.
183 Gordon WS0000024108, paras 88–92; AG/19 WS0000024264, AG/20 WS0000024267
184 AG/24 WS0000024293

9.161 The declaration was that the Board had reasonable assurance in relation to 41 out of the 44 core standards and that it had "robust plans" to address deficits. "Progress" was said to be being made against the developmental standards.

9.162 One of the standards for which the Trust declared compliance was C5c (ensuring clinicians continually update skills and techniques). At the Trust's Board meeting on 20 March, the Board had resolved to change the declaration from non-compliant to compliant. On reviewing the minute, Dr Gordon agreed that the basis of the change was not clear.[185]

9.163 A potentially concerning statement was made in relation to developmental standard D1 (relating continuous and systematic review of activites directly affecting patient safety) where "limited" progress was declared. It was stated that internally generated Dr Foster's reports had:

> *Highlighted that data capture may not reflect actual Trust performance. This being particularly evident in relation to clinical primary and secondary coding.*[186]

9.164 "Insufficient assurance" was declared in relation to core standard C11b, which required the Trust to ensure that healthcare staff participated in mandatory training programmes. This was due to a lack of "consistent uptake" by consultants.

9.165 Insufficient assurance was also declared for Core Standard C13b (systems to ensure consent obtained), and C24 (planned civil emergency response requirements) was not met.

9.166 All other core standards were said to have been complied with, including:

- C1a: making improvements in practice based on local and national experience and information derived from the analysis of incidents;
- C1b: protecting patients through acting upon patient safety notices;
- C4a: keeping patients safe by having systems to ensure that the risk of healthcare acquired infection is reduced with high standards of hygiene and cleanliness;
- C5d: ensuring clinicians participate in regular clinical audit and reviews of clinical services;
- Applying the principles of sound clinical and corporate governance and undertaking systematic risk assessment and risk management.

9.167 The comments made by third parties included the following:

- The WMSHA noted that the national A&E and cancer targets had been met, but that the organisation was underachieving against the MRSA target;

185 Gordon WS0000024110, para 95; AG/23 WS0000024287
186 AG/24 WS0000024297

- The PPIF questioned the declaration of compliance with C14a (patient access to suitable information) and C20a (environments promoting safe and effective care). In relation to the latter, the PPIF referred to the Emergency Assessment Unit (EAU) having been found "all too frequently" not to have met appropriate standards in its unannounced inspections;
- The Staffordshire Health Scrutiny Committee reported concerns about compliance with C4a (hygiene and cleanliness) and C21 (well designed and clean environments) following the PPIF inspection, but had received an assurance from the Trust Chief Executive. They had also been reassured by the apparently positive HCC Hygiene Code inspection;
- The Cannock Chase Health Select Committee reported that it had raised concerns about standards of hygiene and cleanliness and MRSA levels but had been "reassured" by the Trust.

9.168 The HCC's cross-checking resulted in the Trust appearing to be "similar to expected" in relation to 903 indicators; "worse", "much worse" or having a negative comment for 77 items; and "better", "much better" or having a positive comment for 61 items.[187]

9.169 The indicators where the Trust scored "worse than expected" or "much worse than expected", or received "negative comments", are shown in the following table:[188]

Table 9.1: The Trust's negative indicators in the Annual Health Check 2004–2007

Standard	Subject matter	Score	Year
C01a	Confidentiality of the Trust's main local incident reporting system	Negative comment	2006/07
C01a	The ratio of the total number of Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) incidents reported by the NHS Trust to the total number of non-RIDDOR incidents recorded for the Trust	Worse than expected	2005/06
C01a	Consistency of reporting to the National Reporting Learning System	Worse than expected	2006
C02	Intelligence from Local Safeguarding Children Boards	Negative comment	2006/07
C04a	Priorities for improving infection prevention and control identified in action plan	Much worse than expected	2005/06
C04a	How often bed manager liaises with the infection control team	Worse than expected	2005/06
C04a	Restricted anti-microbial susceptibility reporting system	Much worse than expected	2005/06
C04a	Intelligence from strategic health authorities	Negative comment	2006/07
C04a	The proportion of respondents to the adult inpatient survey who stated that in their opinion the hospital room or ward was not very clean or at all clean	Much worse than expected	2006/07
C04a	The proportion of respondents to the adult inpatient survey who stated that as far as they knew, doctors did not wash or clean their hands between touching patients	Much worse than expected	2006/07
C04a	The proportion of respondents to the adult inpatient survey who stated that as far as they knew, nurses did not wash or clean their hands between touching patients	Much worse than expected	2006/07

187 Bardsley WS0000025224, para 45
188 MB/9 WS0000025564

Standard	Subject matter	Score	Year
C04d	Average number of training days for pharmacy staff	Worse than expected	2005/06
C04d	Clinical pharmacy time available per inpatient admission	Worse than expected	2005/06
C05a	In-hospital mortality rates by Health Resource Group chapters: A – nervous system	Much worse than expected	2005/06
C05a	In-hospital mortality rates by Health Resource Group chapters: D – respiratory system	Much worse than expected	2005/06
C05a	In-hospital mortality rates by Health Resource Group chapters: F – digestive system	Much worse than expected	2005/06
C05a	In-hospital mortality rates by Health Resource Group chapters: K – endocrine and metabolic system	Much worse than expected	2005/06
C05a	In-hospital mortality rates by Health Resource Group chapters: S – haematology, infectious diseases, poisoning and non-specific groupings	Much worse than expected	2005/06
C05a	Performance indicator- the proportion of eligible patients receiving thrombolysis treatment within 30 minutes of arriving at hospital	Much worse than expected	2004/05
C05a	NICE progress	Worse than expected	2005/06
C05a	Total 30-day mortality rates by Health Resource Group chapters: A – nervous system	Much worse than expected	2005/06
C05a	Total 30-day mortality rates by Health Resource Group chapters: D – respiratory system	Worse than expected	2005/06
C05a	Total 30-day mortality rates by Health Resource Group chapters: E – cardiac surgery and primary cardiac conditions	Worse than expected	2005/06
C05a	Total 30-day mortality rates by Health Resource Group chapters: F – digestive system	Much worse than expected	2005/06
C05a	Total 30-day mortality rates by Health Resource Group chapters: K – endocrine and metabolic system	Much worse than expected	2005/06
C05a	Total 30-day mortality rates by Health Resource Group chapters: L – urinary tract and male reproductive system	Worse than expected	2005/06
C05a	Total 30-day mortality rates by Health Resource Group chapters: S – haematology, infectious diseases, poisoning and non-specific groupings	Much worse than expected	2005/06
C05a	Emergency readmissions (0–29 days) following operation healthcare resources group chapter – hepato-biliary and pancreatic system (G), ages 65+	Much worse than expected	2005/06
C05a	Emergency readmissions (0–29 days) following operation healthcare resources group chapter – Diseases of childhood (P), ages 0–14	Worse than expected	2005/06
C05b	Patient access to specialist asthma nurses	Worse than expected	2005
C05c	The proportion of respondents to the NHS staff survey who stated that as part of their appraisal or performance development review, they did not agree a personal development plan	Much worse than expected	2006/07
C05c	The proportion of respondents to the NHS staff survey who stated that in the past 12 months they had not taken part in courses (internal or external) paid for by their trust	Worse than expected	2006/07
C05c	The proportion of respondents to the NHS staff survey, who stated they did not have clear, planned goals and objectives for their job	Worse than expected	2006/07
C05c	Average number of training days for pharmacy staff	Worse than expected	2005/06
C06	Intelligence from local engagement	Negative comment	2006/07
C07ac	Key line of enquiry 4.1 – the organisation manages its significant business risks	Worse than expected	2005/06
C07ac	Intelligence from local engagement	Negative comment	2006/07

Standard	Subject matter	Score	Year
C07ac	Intelligence from local engagement	Negative comment	2006/07
C07ac	Intelligence from local engagement	Negative comment	2006/07
C07e	The proportion of respondents to the NHS staff survey who stated that their trust did not take effective action if staff were sexually harassed	Much worse than expected	2006/07
C07e	Trusts which have published their employment monitoring statistics on race equality on their website	Worse than expected	2007
C07e	Trusts which have published outcomes of race equality impact assessments on their website	Worse than expected	2007
C08b	The proportion of respondents to the NHS staff survey who stated that, as part of their appraisal or performance development review, they did not agree a personal development plan	Much worse than expected	2006/07
C08b	The proportion of respondents to the NHS staff survey who stated that their trust does not have access to a childcare coordinator	Worse than expected	2006/07
C08b	The proportion of respondents to the NHS staff survey who stated that their trust does not provide support for carers of dependents other than children	Worse than expected	2006/07
C11a	Performance indicator – workforce indicator for acute trust	Much worse than expected	2004/05
C11a	Intelligence from local engagement	Negative comment	2006/07
C11c	The proportion of respondents to the NHS staff survey who stated that in the past 12 months they had not taken part in taught courses (internal or external) provided by their trust	Worse than expected	2006/07
C11c	The proportion of respondents to the NHS staff survey who stated that the training, learning or development they had received in the past 12 months had not helped them to stay up to date with their job	Worse than expected	2006/07
C12	The proportion of breast multidisciplinary team measures met for standard C12	Much worse than expected	2007
C12	The proportion of upper gastrointestinal multidisciplinary team measures met for standard C12	Much worse than expected	2007
C13b	The proportion of respondents to the outpatient survey who stated that, while in the outpatient department, they were not given any information about their treatment, or condition	Worse than expected	2004/05
C13b	The proportion of respondents to the outpatient survey who stated that before the treatment, a member of staff did not explain what would happen	Worse than expected	2004/05
C14a	Intelligence from patient and public involvement forums	Negative comment	2006/07
C16	The proportion of respondents to the adult inpatient survey who stated that before their operation/procedure they were not told how they could expect to feel after they had the operation/procedure	Much worse than expected	2006/07
C18	Patient access to specialist asthma nurses	Worse than expected	2005
C18	Patient access to specialist chronic obstructive pulmonary disease nurses	Worse than expected	2005
C18	Waiting times for rapid access chest pain clinic	Much worse than expected	2005/06
C18	Length of stay in an admission unit prior to transfer: percentage over 48 hours	Worse than expected	2005/06
C18	The proportion of more than 12-week waits for first outpatient attendance for ENT	Worse than expected	2006
C18	The proportion of more than 12-week waits for first outpatient attendance for ophthalmology	Much worse than expected	2006
C18	The proportion of more than 12-week waits for first outpatient attendance for thoracic medicine	Worse than expected	2006

Standard	Subject matter	Score	Year
C18	The proportion of more than 12-week waits for first outpatient attendance for elderly care	Much worse than expected	2006
C20a	The proportion of respondents to the NHS staff survey who stated that their trust did not take effective action if staff were sexually harassed	Much worse than expected	2006/07
C20a	The ratio of number of fires recorded as required by FIRECODE to number of false alarms	Much worse than expected	2005/06
C20a	Intelligence from local engagement	Negative comment	2006/07
C20a	Intelligence from patient and public involvement forums	Negative comment	2006/07
C20a	Intelligence from local engagement	Negative comment	2006/07
C21	The proportion of respondents to the adult inpatient survey who stated that in their opinion the hospital room or ward was not very clean or not at all clean	Much worse than expected	2006/07
C21	The proportion of respondents to the adult inpatient survey who stated that as far as they knew, doctors did not wash or clean their hands between touching patients	Much worse than expected	2006/07
C21	The proportion of respondents to the adult inpatient survey who stated that as far as they knew, nurses did not wash or clean their hands between touching patients	Much worse than expected	2006/07
C21	Intelligence from local engagement	Negative comment	2006/07
C23	Performance indicator – the proportion of eligible patients receiving thrombolysis treatment within 30 minutes of arriving at hospital	Much worse than expected	2004/05
C23	Smoke-free NHS recording of smoking status and reducing smoking (does the trust routinely record the smoking status of all adult inpatients?)	Worse than expected	2006
C23	Total 30-day mortality rates by Healthcare Resource Group chapters: E – cardiac surgery[188] and primary cardiac conditions	Worse than expected	2005/06
C23	Emergency readmissions (0–29 days) following operation: Health Resource Group chapter – diseases of childhood (P), ages 0–14	Worse than expected	2005/06
C23	Intelligence from local engagement	Negative comment	2006/07

9.170 It can be seen that a large number of the mortality indicators aligned to Standard C5a were poor: in five diagnostic groups the Trust's mortality was much worse than expected. These received a lower weighting than might have been expected because they related to returns for 2005/06, and therefore were not regarded as current. It was this perceived deficiency that left the HCC to develop its own mortality outliers analysis.[190]

9.171 The Trust was selected for a risk-based CSA, presumably because of the concerning data on mortality, but also because of the concerns reported the previous year about governance (see above). Five core standards were identified for assessment:

- C6 – cooperation with healthcare organisations;
- C7a and c – applying principles of sound clinical and corporate governance and undertaking systematic risk assessment and management;
- C7e – challenging discrimination and respect for human rights (bullying);

189 The Trust did not perform cardiac surgery and as such this category related to cardiac diseases treated by A&E, GPs and cardiologists
190 Bardsley WS0000025225, para 46

- C20a – healthcare services provided in environments promoting effective care and optimising health outcomes by being a safe and secure environment;
- C21 – being well designed and maintained.[191]

9.172 The assessment visit took place on 18 July 2007 and was conducted by two assessors chosen because they were not local to the Trust. Again, there was no element of physical inspection involved, but the presentation and examination of a large quantity of documents, largely concerned with process. The conclusion of their report was that the Trust had complied with all five core standards checked.[192] In many cases the assessment relied on the judgement of other organisations, such as the Audit Commission's Auditor's Local Evaluation (ALE) reports. There was little indication that any examination of the correct application of a system either took place or was expected. For example, one line of inquiry was that "The healthcare organisation should be able to demonstrate that wards and departments are clean and kept clean."[193]

9.173 The untutored outsider might have expected a view of at least part of the premises, feedback from patients and so on, but the evidence resulting in the assessors finding compliance consisted of examination of some 24 documents evidencing:

- A Patient Environment Action Team (PEAT) report scoring the Trust as "good";
- The fact that the PPIF conducted audits and visits, but with no reference being made to the concerns expressed following them;
- A formal agreement between the Trust and PPIF to "underpin" their "partnership work";
- PPIF representation on the Trust's Infection Control Committee;
- The Trust's annual audit for environmental infection control;
- The Trust's Clinical Quality and Effectiveness Group monitoring of infection control work;
- The inclusion of performance monitoring in the cleaning contracts;
- Bespoke cleaning schedules in all areas;
- Various policies which were said to demonstrate that the wards were kept clean;
- The HCC's own visit and ensuing letter referred to above.[194]

9.174 While the Inquiry has not examined the content of all these documents, the assessors' report contains no suggestion that the content was examined or that they asked themselves the question: "Are the wards in fact clean as a result of these policies and processes?".

9.175 Again adopting the technique described above, the assessment team also found that the Trust was in compliance with the requirements in the core standards for clinical governance. Shelagh Hawkins commented on this to the Inquiry:

191 MB/10 WS0000025611
192 MB/10 WS0000025611
193 MB/10 WS0000025655
194 MB/10 WS0000025655–6

With the benefit of hindsight, if the Trust had stated that their governance issues had been resolved at this point, I would have thought that Helen Moss was a "miracle worker".[195]

9.176 As noted above, a year after this assessment Dr Wood was to determine in the course of her investigation that at the time of this assessment the Trust was in fact "in chaos". She considered that the assessment had been wrong, not because of incompetence on the part of the assessors but because of the system they were expected to apply:

Q: I mean, in terms of what you found during the course of your investigation a year later, it's difficult to see how as a reality, rather than procedures and processes, it's difficult to see how as a reality some of the those core standards were in fact met at all. Is that fair comment?

A. I think it is fair comment, except again you would probably need to go back to whether the core standards were as they should have been in the first place. Even more to the point, how the measurement of those then rolled out, because, I suppose, my fundamental point is they weren't really tackling what needed to be measured.[196]

Healthcare Commission patient and staff surveys

9.177 The information about the Trust contained in the HCC patient and staff surveys report produced in 2007 from information obtained in 2006 has been described in *Chapter 1: Warning signs*. It came within the worst 20% of trusts in the country in the answers to 10 important questions in the patient survey. The staff survey was no more encouraging. Similar concerns were apparent from a survey taken in 2007, the results of which were published in 2008.

9.178 There is no evidence that the surveys resulted in any concerns at the HCC. The survey results were included in the indicators referred to above. One reason they may have been discounted is that by the time the results were released they were potentially out of date. However, the information will have related to the year under review; therefore, the unfortunate fact of the matter is that the experiences of staff and patients counted for less than the presence of documented policies and procedures.

Healthcare Commission regional offices

9.179 The HCC had four regional offices, the nearest to the Trust being in Manchester. Contact was made regularly with each trust by a regional manager; in the case of the Trust, this was Dr Gordon. Reporting to her was a regional assessor for the Trust, Shelagh Hawkins. She visited each of the trusts in her area once a month and was available to carry out CSAs.

195 Hawkins WS0000026358, para 80
196 Wood T81.81–82

She could also recommend that CSAs be performed on trusts with which she had contact. Ms Hawkins had a team leader who would telephone the Strategic Health Authority (SHA) weekly to discuss the HCC's concerns about trusts, as the SHA was the performance manager.

9.180 Some assessors attended their trusts' board meetings but Ms Hawkins did not. Dr Gordon did attend meetings with the clinical governance leads of each of her trusts, including the Trust.[197]

9.181 Engagement forms would be completed and sent on to the HCC's centrally based informatics team to be included in its analysis. However, the forms were not shared with the central investigations team.[198]

9.182 Assessors were discouraged from visiting wards or making anything that could be interpreted as a clinical recommendation in relation to NHS organisations. By contrast, they were expected to visit the wards of private hospitals and to make unannounced visits to them.[199]

9.183 Until 2008, the HCC did not have a means of systematically feeding local information from the assessors throughout the organisation. It then began developing Organisational Risk Profiles which appear to have been the precursor for Quality and Risk Pofile (QRP) used by the Care Quality Commission (CQC).

9.184 Some of the contacts between regional staff and the Trust have been described above. Although it was possible for them to ask for an "initial consideration" by an investigations team, it is clear that no one from the regional office developed concerns about the Trust substantially before the beginning of the HCC investigation, which was not in any way triggered by them. For example, Dr Gordon presented a report on the West Midlands area to the Commission on 22 November 2007.[200] No specific issues of concern were highlighted in relation to the Trust, although problems with some others were.

9.185 Relevant witnesses were asked if there had been a danger of the regional team becoming too close to its trusts, rather than remaining the vigilant and objective local eyes and ears of the regulator. Anna Walker denied that this was the case, emphasising the importance of the supportive role which a regulator can, and in her view, should, play:

197 Gordon WS0000024091, paras 17–18
198 Gordon WS0000024091, para 20
199 Hawkins WS0000026337, paras 17 and 21
200 HCC0056000396, Minutes of the HCC meeting (22 November 2007)

A. Well, my experience of regulation, very deeply, actually, is that you do need to act in partnership, at one level, with the sector that you're regulating, in the sense that you need to understand why they think or are doing what they are, whilst still continuing to answer the questions. And at some level regulation has to be acceptable, in the sense that people understand what it's doing and why overall. Having said that, I have never had difficulty as a regulator from exploring and seeking to work in partnership, where the issues still remain issues for the regulator, standing back and saying, "Absolutely, we now have to use our regulatory powers". I actually think the Healthcare Commission was good at doing that.[201]

... I would be concerned if you were to be drawing conclusions that, although this relationship – or perhaps "partnership" is not the right word, but working alongside those you're regulating was wrong in all circumstances, because if improvement is what one's seeking to achieve, the regulator, with hopefully their knowledge of what is good and their knowledge of what others are achieving, can actually help an organisation with the right attitude to improve. And to take the relationship between the regulated and the regulator, such that that couldn't happen I think something quite significant would be lost.[202]

9.186 Nigel Ellis did not consider that the necessary formality of a regulator in its relationship with a regulated entity was inconsistent with a close working relationship, but he recognised the danger:

Yes, you need to work together, of course you need to be constructive in your day-to-day working relationships. But at no point can you allow that to become informal, otherwise you lose the sense of what you're doing and the professional distance between the two organisations, whether it's a strategic health authority or whether it's a trust or whether it's a PCT, or what have you.

Closeness, therefore, if it represents day-to-day contact, I think it's something that can be managed. It's part of the job; shouldn't be a big deal. Informality, though, and what can follow, which is lack of professional objectivity, is to be guarded against I think at all stages. And I do think that there is always a risk the regulator needs to be aware that that can happen. I'm not saying that it did.[203]

9.187 Martin Bardsley also saw the dangers and suggested that objective analysis of data of the sort that he managed was at least part of the answer:

201 A Walker T83.116
202 A Walker T83.147
203 Ellis T80.70

I think with any operational field force for a regulator you run a tension between the advantages of having people close to the ground, close to the trusts, in touch with local community leaders, which is the positive side, and able to think about and synthesise evidence and intelligence locally; the good side. The negative side is the danger that they become accepting of local organisations. They make assumptions which they may not want to do, and in a sense that's when we get into a world of regulatory capture when they may not be providing the right level of effective challenge. I think it's been widely recognised as a general problem for other regulators and they have to be mindful of it. And I think some of the structured analysis of information is one way that you help mitigate some of those effects.[204]

9.188 Dr Gordon also accepted that a balance had to be struck.[205]

9.189 Dr Wood, from her general experience as an investigator, and not talking specifically about the regional team responsible for the Trust, was rather more sceptical:

In terms of your question about relationships, I felt it sometimes went both ways. So in some instances I think they (the regional assessors) did go a bit native. They perhaps, from my perspective, became too sympathetic to the problems of trusts and too remote from the experience of patients. But I think in other instances they might actually, to use the vernacular, sort of take against a trust for reasons that were not entirely clear. So I just felt they didn't have perhaps the objectivity that we had the luxury of having at national level.[206]

9.190 The need to keep some distance may have led to Shelagh Hawkins's feeling of frustration that she was not allowed to intervene in trusts to correct issues as she immediately saw them, for fear of being seen to be interfering or undertaking inappropriate performance management.[207]

The concordat

9.191 The HCC's relationships with other organisations were defined in May 2006 by the concordat which was signed by HCC, the Audit Commission, the HSE, the Health Protection Agency (HPA) and the NHSLA, among others. By March 2009 the concordat had 20 signatories. The May 2006 concordat set out what bodies providing healthcare in England could expect from the main inspecting bodies and stated that it was designed to support the improvement of services for the public and to reduce unnecessary burdens on front-line staff. The concordat

204 Bardsley T82.172
205 Gordon WS0000024135–6, para 197
206 Wood T81.31–32
207 Hawkins WS0000026343, para 37

agreed 10 objectives for healthcare regulatory bodies which had been developed by the inspecting bodies who were signatories to the agreement. These were:[208]

- Inspections are coordinated with other reviews and collections of data;
- Inspections focus on the experiences of patients, other service users and carers;
- Inspections support improvements in quality and performance;
- Inspecting bodies continuously improve their methods;
- Inspections are independent, consistent and fair;
- Inspections are targeted and proportionate;
- Inspections are transparent and accountable;
- Inspections use coordinated and proportionate methods of enforcement;
- Inspectors are suitably qualified, trained and skilled;
- Inspecting bodies continuously monitor their policies in line with the concordat.

Relations with Monitor

9.192 Monitor refused to join the Concordat. Dr William Moyes, who was Executive Chairman of Monitor at the time, gave reasons for this. He stated that although Monitor never thought that the concordat was a bad initiative, it felt that it was simply not of assistance to it in discharging its statutory obligations. His view was that, firstly, the problem which the concordat was seeking to resolve, namely multiple reporting and inspection regimes which could detract from day-to-day affairs, was addressed by Monitor in relation to FTs by its rationalising of the amount of information each trust needed to provide to the DH. Secondly, he believed that the operation of the concordat would have been to channel all requests for information and visits through the HCC, which would have hindered Monitor's ability to run its own compliance system.[209]

9.193 However, the HCC's Investigations Committee had signed a protocol with Monitor and the DH in October 2005.[210] This made provision for how the two organisations would work together in the event of an initial consideration or an investigation involving an FT. Among the matters agreed were the following:

- The HCC Investigations Team was to inform a named person at Monitor that "they had received a request for an investigation into a Foundation Trust, or a trust that is known to be applying for foundation status".
- The team was to keep Monitor informed of visits (whether announced or unannounced) to FTs to carry out inspections (paragraph 8);
- The HCC was to inform the named contact at Monitor of its decision about the need for an investigation and of any recommendations made in lieu of an investigation (paragraph 9);

208 IK/3 WS0000026049
209 Moyes WS0000039705, para 218
210 NE/10 WS0000027868

- The team was to inform the named contact at Monitor of decisions to approve an investigation of an FT (paragraph 10);
- Monitor was to be provided with the draft investigation report and any recommendations, to allow it to comment on matters relating to its function (paragraph 13).

9.194 Monitor and the HCC entered into a separate memorandum of understanding in September 2006.[211] This recited HCC's obligation to inform Monitor if it formed the view that an FT had significant failings in the provision of healthcare, or in the running of an FT (paragraph 8), and the duty of cooperation (paragraph 11).

9.195 A general obligation on the HCC to inform Monitor "about the provision of healthcare by and for NHS Foundation Trusts" was recognised (paragraph 9).

9.196 The memorandum also stated (paragraph 14) that there needed to be:

> *a. The proper exchange of information in relation to NHS Foundation Trusts* or NHS Trusts/ public benefit corporations that have applied for foundation trust status; [emphasis supplied]
>
> *b. Effective coordination in respect of failing NHS Foundation Trusts; and*
>
> *c. A preparedness to support each other in the discharge of their respective responsibilities* [para 14].

9.197 The organisations undertook to keep each other informed "promptly and fully" about developments of interest to each (paragraph 26), and to inform each other without delay of matters which might require action by, or a response from, the other party (paragraph 28).

9.198 Amendments were made to the protocol in December 2007. In his recommendation to the Investigations Committee, Nigel Ellis suggested that the protocol (and a parallel arrangement with the DH) should record the existing practice of bringing to the attention of the trust concerned, the Strategic Health Authority (SHA) and Monitor:

> *... [a]ny specific urgent concerns about the safety of patients and/or the quality of services that may arise during the course of the investigation. The important point to stress is that we do not and will not delay formal communication of our concerns to the relevant bodies.*[212]

9.199 While some of the drafting could, in retrospect, have been clearer, there can be no doubt that the intention of the memorandum and the protocol was that information should be shared not

211 MON00030026931, *Memorandum of Understanding between the HCC and Monitor* (September 2006)
212 NE/9 WS0000027856

only about existing FTs, but about trusts applying for FT status. Indeed the process leading to the protocol appears to have been informed by the perceived need to exchange information about applicants. Anna Walker told the Inquiry:

> *... to begin with, Monitor – and I spent a lot of time with Bill Moyes and we both put teams in place to try and ensure that Monitor and the Healthcare Commission worked more effectively together. The protocol was the beginning of that and there were a lot of further developments, and I believe things changed really very significantly ...*
>
> *What happened to Monitor was that to begin with there were a series of hospitals or trusts where it was quite clear that they were ready for foundation trust status. Monitor then began to look at those where the case was less clear-cut, actually, and they themselves would recognise that and indeed talked to us about that. That was the point at which I think it became particularly important for there to have been a protocol in place, a process in place which ensured that there was more interaction. But I don't think it was a lack of willingness on people's part.*[213]

9.200 As will be seen, the protocols did not result in highly relevant information about the HCC's intentions being shared with Monitor at a crucial stage of its assessment of the Trust's FT application.

Complaints handling

Legislative framework

9.201 Under regulations,[214] the HCC was given the duty of considering complaints where:

- The complainant was not satisfied with the result of an investigation of a complaint by an NHS body, or an independent provider with whom NHS arrangements had been made;
- For any reason, such an investigation had not been completed within six months of the date of the complaint;
- A complaints manager had decided not to investigate a complaint on the ground that it had not been made within the statutory time limits.

9.202 Such an application to the HCC had to be made within two months of receiving a response from the organisation of which the individual had complained or as soon as reasonably practicable after that date.

213 A Walker T83.91–92
214 Health and Social Care (Community Health and Standards) Act 2003, section 113; National Health Service (Complaints) Regulations 2004 [SI 2004/1768], Reg 14

9.203 The procedure to be followed by the HCC as laid down by the regulations was somewhat elaborate:

- In deciding how a complaint was to be handled the HCC had to take into account:
 - The views of the complainant;
 - The views of the body complained against;
 - Where that body was an FT, the views of Monitor;
 - Any investigation of the complaint, whether under these regulations or otherwise;
 - Any other relevant circumstances.[215]
- Having gathered that information, the HCC had to decide whether to:
 - Take no further action;
 - Make recommendations to the body complained against as to what action it might take to resolve;
 - Undertake a further investigation of its own;
 - Consider the subject matter of the complaint as part of any other investigation being carried out in the exercise of any of its functions;
 - Refer the complaint to a "health regulatory body" or, if the complaint was about an FT, to Monitor;
 - Refer the complaint to the Health Service Ombudsman (called "the Commissioner" in the regulations).[216]

9.204 There was no express power to undertake any follow-up of the implementation of recommendations, but from May 2007 the HCC set up a tracking system for this purpose.[217]

The challenges imposed on the Healthcare Commission

Lack of preparation due to "slippage and scramble"

9.205 The initial experience of the HCC was considered in a report by the Health Service Ombudsman published in 2005, already quoted above. She painted a vivid picture of the problems with which the HCC was faced. It is right to quote this report extensively, as nothing in the evidence before this Inquiry has suggested any need to revise the critical opinion reached then:[218]

215 National Health Service (Complaints) Regulations 2004 [SI 2004/1768], Reg 16(1)
216 National Health Service (Complaints) Regulations 2004 [SI 2004/1768], Reg 16(2)
217 Fry WS0000026578, para 44
218 MF/2 WS0000026729, A Report on Reform of the NHS Complaints Procedures in England (March 2005)

85. The result of the scrambles for change was often confusion. The implementation of the 2004 regulations and the transfer of responsibility for the second stage of the procedure to the Healthcare Commission exemplify this. The Healthcare Commission formally came into existence in April 2004, although it had operated in shadow form for some time before that. Its complaints handling role was entirely new. At one point it had been hoped it could take on complaints from April 2004. However consultation on new draft regulations did not begin until December 2003 and this delayed their planned implementation until 1 June 2004. The original draft contained detailed changes relating to local resolution as well as defining the Healthcare Commission's new role. In March 2004 we raised concerns that it would be difficult, if not impossible, for the Healthcare Commission to deliver an effective complaints handling process from 1 June 2004 and that this risked bringing the new arrangements into disrepute from the outset.

86. The Department of Health gave little extra time to the Healthcare Commission to prepare for their new role, even though major changes to local resolution had been postponed to 2005. By May 2004 it had been decided to introduce the changes affecting the Healthcare Commission on 1 July. In fact the relevant regulations were not laid until 9 July and came into force on 30 July.

87. The rushed introduction, and consequent lack of preparedness, impacted both on complainants and those trying to operate the procedure at all levels ... Implementing regulations three weeks after they were laid before Parliament gave inadequate time for the public, NHS staff, advisers and voluntary agencies to understand them and use them effectively. Guidance ... was not issued until 19 August, nearly three weeks after the regulations came into force.

88. Given that public confidence was already low, as shown by the [2001 report] *we expressed our concern at the time that a bad start to the new system was likely to create a further loss in public confidence which would be difficult to overcome.*

89. The Healthcare Commission had to build up their capacity to handle the second stage from scratch ...

90 ... The overall effect for complainants has been a severe delay in having their complaints addressed ...

Inaccurate prediction of workload

9.206 From the Ombudsman's report, and a later report by the National Audit Office, it is clear that the HCC was misled as to the number of complaints to expect.[219] The DH estimated that there would be between 3,500 and 5,000 requests a year, based on a presumption that the number would be comparable to those received under the previous system, which was understood to be about 3,200 cases a year.[220] The HCC Board was informed in November 2004 that whereas

219 MF/8 WS0000026900, para 2.37
220 Fry WS0000026572, para 21

previously the rate of complaints had been 3,000 a year it was now running at 7,500 annually.[221] In fact the HCC received over 8,000 complaints in the initial year, levelling out to some 600 cases a month (or 7,200 a year).[222]

9.207 Not surprisingly, the HCC did not to begin with have enough staff or independent clinical advice to deal with this volume, resulting in a large backlog.

9.208 Because of the uncertainties surrounding the commencement date of the complaints regulations, the HCC began to receive complaints before it had the power to deal with them. It was decided it would not be productive to send these complainants away, so their complaints were retained pending the coming into force of the regulations. By that time, a backlog of around 500 complaints had built up.[223]

9.209 By 2006 the staff employed to deal with complaints had increased from about 70 at the start to 160, and the proportion of the HCC's budget taken up with this activity was about 15%.[224]

9.210 By May 2006 there were 5,384 open cases, of which 835 had been open for more than 12 months.[225]

9.211 Because of the lack of staff and the number of complaints, the pressure of work was considerable. Marcia Fry told the Inquiry that in 2004 and 2005 the complaints team was "overwhelmed".

9.212 This meant that complaints information was not being analysed.[226] Further, the team did not have the resources to check whether action plans arising out of complaints were actually being implemented, until about March 2007.[227] Before then the team would generally take an action plan at face value and assume that it was being implemented, unless there was a specific complaint that a plan was not being followed through. In May 2007 this problem was tackled by the introduction of a tracking system to follow up on the implementation of recommendations.[228]

9.213 The evidence before the Inquiry also suggested that there was a risk that inferences with regard to general patient safety to be gained from a single but serious complaint about a provider might be missed. Marcia Fry agreed that it was possible that those employed to look at letters of complaint when they first arrived might not be sufficiently experienced to

221 MF/9 WS0000026904, page 3
222 Fry WS0000026572, para 21
223 Fry WS0000026573, para 24
224 Fry WS0000026573, paras 23–27
225 MF/8 WS0000026900, para 2.38
226 Fry T79.130
227 Fry T79.142
228 Fry WS0000026578, para 44

appreciate their significance and that therefore they could remain unallocated to a case manager for an appreciable time.[229]

Negative effect of proposed abolition and reform

9.214 In June 2007 the DH announced proposals to change the system yet again, seeking to have a comprehensive single complaints system across health and social care, and to remove the second stage from the HCC, leaving the Ombudsman to deal with all reviews.[230] By this time the proposed abolition of the HCC and the creation of the Care Quality Commission (CQC) had been announced, leading to the inevitable drop in morale among staff. Marcia Fry told the Inquiry:

> *For those of us who had been in healthcare for some years it was a case of "here we go again". Of course the news affected HCC employees as morale dipped and people worried for their jobs, knowing that the structure would be different. This was particularly true for those who worked in the complaints team as there was no successor body to transfer to. Having said this ... the quality of the work remained high.*[231]

Healthcare Commission performance on complaints handling

9.215 By July 2007 there were 2,363 open cases of which 67 had been open for more than 12 months.[232] This was reduced by the beginning of 2008 to 1,740 cases of which only eight were of more than 12 months standing.[233]

9.216 By early 2009 most cases were being closed within six months.[234]

9.217 In its final report on complaints, the figures showed that the HCC had dealt with about 7,500 second-stage complaints over its lifetime. Of these, 95% had been resolved within six months, and most cases had been closed within a similar period. 30% of complaints were upheld.[235]

9.218 However, the bald figures do not do justice to the difficulties inflicted on complainants by delays. Some of these will be considered in the context of the complaints against the Trust (below).

9.219 The HCC was so overwhelmed with the workload thrust upon it initially that little use was or could have been made, in terms of its regulatory functions, of the information contained in

229 Fry T79.151
230 *Making Experiences Count: A new approach to responding to complaints* (June 2007), Department of Health
231 Fry WS0000026574, para 30
232 Fry WS0000026578, para 46
233 Fry WS0000026578, para 49
234 Fry WS0000026583, para 65
235 MF/27 WS0000027385, pages 2–3

the complaints it received.[236] The most it was able to do was to draw out national learning points, but it could not analyse trends or patterns at individual trusts.[237]

9.220 So far as following up substantiated individual complaints was concerned, it appears that generally the HCC was satisfied by the production of a plausible action plan appearing to address the issues raised by the complaint. Ms Fry's justification of this was:

> *When you've asked an organisation that has a – professionals leading it and a responsibility to their public, I think it's reasonable to expect them to do what they've said they will do.*[238]

9.221 There was little, if any, proactive follow-up to confirm that the action plans had in fact been implemented.[239] The information about the complaint would be sent to the relevant local team, but it is not clear what, if anything, expected to do.

Complaints against the Trust

9.222 In a minute of the HCC Investigations Committee meeting of 9 August 2006, the Trust was said to be the second highest in the country in relation to the number of complaints being referred back to it for further work: about 68% (19 out of 28) of complaints about the Trust received by the HCC fell into this category.[240]

9.223 Valerie Harrison of People of Hertfordshire want Equal Rights (POhWER) the Independent Complaints Advisory Service (ICAS) relevant to the Trust, provided the Inquiry with a helpful analysis of 12 second-stage complaints against the Trust made between 2005 and 2009. [241] The shortest time for second-stage resolution in these cases was 13 months and the longest 18. Ms Harrison considered that unacceptable.[242] The protracted nature of the process to which complainants were subjected can be illustrated by reference to a sample of these cases:

- A complaint about a patient falling out of her bed was made in December 2005 and was referred back to the Trust in February 2007. Following a meeting with Trust management, the complainant took the case to the Ombudsman who took a year to decide not to uphold the complaint. The process took 41 months, of which a year was taken up at the HCC stage;
- A complaint by the husband of a patient who died from cancer concerning misdiagnosis and subsequent treatment was made on 11 September 2003. The complaint, having been

236 Fry T79.130
237 Fry T79.129
238 Fry T79.143
239 Fry T79.142–143
240 MF/10 WS0000026917
241 Harrison T28.109; POW00010000031, *HC/PHSO case summaries* (August 2010), POhWER
242 Harrison T28.123

referred to the HCC in January 2004, was not referred back to the Trust with the HCC's recommendations until some 33 months later, in September 2006. The complainant was unhappy with the Trust's response to this, and the matter was sent to the Ombudsman who then referred the case back to the HCC, as it did not consider the second stage of the complaint system completed. The HCC reconsidered the case but decided to close it. The complaint was then sent back to the Ombudsman by the complainant. The Ombudsman then took 13 months before deciding to uphold the complaint. The matter was finally closed following a meeting with the Chief Executive of the Trust in April 2010. The process took a total of 80 months before it was finally resolved;

- A complaint over the misdiagnosis of a hip problem was made on 19 September 2006. The Trust took six months to respond to the complaint and the HCC took 12 months to produce a report with recommendations to the Trust. The complainant was unhappy with the Trust's response to these recommendations and the matter was finally referred to the Ombudsman in May 2009. The process was not completed until August 2009, some 34 months after the initial complaint had been made.

Healthcare Commission investigation of the Trust

Investigations generally

9.224 Before the investigation into the Trust, the last conducted by the HCC before it was abolished, it had conducted 16 investigations. These included:

- Maidstone & Tunbridge Wells NHS Trust: *C. difficile*;
- Stoke Mandeville Hospital Buckinghamshire NHS Trust;
- Royal Wolverhampton NHS Trust: maternity services;
- Northwick Park Hospital North West London Hospitals NHS Trust: two investigations into governance and the deaths of 10 mothers;
- Cornwall Partnership NHS Trust: treatment of patients with learning difficulties;
- Sutton and Merton Primary Care Trust;
- Mid Cheshire Hospitals NHS Trust: care of older people.

9.225 In its own evaluation of its inspections the HCC said this in July 2008, before the investigation of the Trust was complete:

> *The Commission's interventions and investigations have been highly visible and effective. They have promoted improvement in the individual trust and across the provision of healthcare services. They have sent "shockwaves" across healthcare services. The capacity to probe trusts in depth in this way, and especially the power to recommend special measures, add significant force to the Commission's regulatory model complementing the broad based assurance provided by the annual health check.*

The Commission's interventions and especially its investigations have a high (and increasing) public profile. It has identified poor, shocking and sometimes illegal practices ...[243]

9.226 The Commission identified areas where it needed to improve its performance in relation to investigations:[244]

- It needed to spot issues earlier and move more quickly.
- It needed to use rapid interventions where these were judged to be more appropriate than full-scale investigations.
- A better dissemination of the lessons learned was required.
- Data on high rates of mortality and other benchmarking information had to be used to follow up trusts where there might be problems that have not yet been properly identified.

Knowledge of the Trust's application for foundation trust status

9.227 The HCC at regional office level knew of the Trust's application. Shelagh Hawkins told the Inquiry:

I was aware that the trust had applied for this [FT status] *and at this time there was a drive for all trusts to become Foundation Trusts ... I was not aware of the timing of the application ... I was not however involved in this and no one asked me whether I had an opinion in relation to the Trust's application.*[245]

9.228 Unfortunately, the higher echelons of the HCC did not know of the Trust's application. According to Anna Walker the first she heard of the Trust's application, and, by then, its authorisation, was in a conversation on another topic with a Director of Monitor in March 2008 (very shortly before the public announcement of the investigation) in the course of which the subject of the Trust came up. The Director had said:

243 RC/3 WS0000043591; *Making a difference?* (July 2008), HCC
244 RC/3 WS0000043591–592; *Making a difference?* (July 2008), HCC, pages 17–18
245 Hawkins WS0000026264, para 102

... that Monitor had seriously debated at Board level during the application whether the Trust was ready for foundation trust status. I recall responding saying that it was a pity [they]*, or someone else from Monitor, had not informed the Healthcare commission, that the Trust was going through this application process as we would have told them there was a potential investigation in the pipeline. As a result of this conversation, both* [they] *and I recognised that there should be a process in place to make sure that Monitor and the Healthcare Commission exchanged views on potential applications for foundation trust status.*[246]

9.229 Anna Walker told the Inquiry that there was no formal system in place to ensure that this sort of information was exchanged. She had not known until after the evidence was produced to the Inquiry of the fact that the regional team had known of the application but had not disseminated the information more widely. She accepted that this was the sort of thing likely to happen in the absence of a formal system.[247]

Mortality alerts

Development of the Healthcare Commission's own analysis and cooperation with the Dr Foster Unit

9.230 HCC developed its own method of identifying mortality outliers which was not reliant on the output of the Dr Foster Unit (DFU). It did so because it felt that use of mortality rates for specific groups of patients was more likely to disclose problems than the overall Hospital Standardised Mortality Ratio (HSMR).

9.231 At about the same time, the HCC entered into discussions with Professor Sir Brian Jarman and Dr Paul Aylin at DFU. It emerged that they had access to more up-to-date and "clean" data from the Secondary Uses Service (SUS), which was available more quickly than the Hospital Episode Statistics (HES). They agreed that the DFU would send its alerts for individual trusts to the HCC for consideration by HCC's Mortality Outliers Panel. This panel was set up in July 2007 to look proactively at available mortality data in order to highlight concerns which might represent a risk to patient safety. The panel was therefore able to consider both DFU alerts and those being generated by the HCC's own outlier process.[248]

9.232 At the time the alerts in relation to the Trust arose, the HCC's mortality programme was still in development. The first alert generated in relation to the Trust was in fact the first ever produced.

246 A Walker WS0000028594, para 180
247 A Walker T83.85–86
248 Ellis WS0000027762, paras 52–56

Alert for jejunum operations

9.233 The first alert about the Trust generated by the DFU was in relation to jejunum operations (11 deaths as opposed to an expected 4.9) and was sent to the Trust on 3 July 2007.[249] This information was forwarded by HCC's informatics team to Dr Gordon at the regional office on 11 July 2007.[250] Shelagh Hawkins responded that intelligence suggested that more cases might be being dealt with by the Trust than usual because the University Hospital of North Staffordshire (UHNS) was not accepting transfers, meaning that the Trust was having to deal with a more specialised type of case. She also expressed concerns about the quality of consultant appraisal at the Trust.[251]

9.234 The Mortality Outliers Panel considered this alert on 21 August. The HCC's own analysis suggested that coding could be an issue and also that a high proportion of the operations might be performed out of hours.[252]

9.235 On 23 August, the HCC wrote its first alert letter to the Trust in connection with the information about jejunum operations. It sought answers to a number of questions, including a request for the Trust's explanation of the figures, what review the Trust had conducted, what proportion of operations were performed out of hours and the seniority of the surgeon involved. The Trust was required to produce the information by 7 September.[253]

9.236 On 3 September, Martin Yeates replied that the Trust had received the alert and that there had been 11 deaths between June 2006 and July 2007 out of 33 admissions.[254] He said that the Trust's analysis suggested the patients were higher-risk, older and mainly admitted as emergencies. He promised to send the Trust's full report once it had been completed. No such report was forthcoming and it was chased by the HCC on 17 September and 25 October 2007.[255]

Alert for aneurysms

9.237 A second alert was received from the DFU in August 2007 in relation to aortic, peripheral and visceral artery aneurysms. This was to the effect that there had been 11 deaths in this group against an expectation of 5.8 (although the confidence interval was wide with a lower end in the "expected" range). The HCC's analysis suggested that coding issues could not account for the figures and that its mortality was consistently high across all the diagnostic codes included in this group.[256] The HCC sent a new alert letter to the Trust on 10 October 2007.[257] It asked, among other things, whether the Trust had conducted a case note review and

249 Bardsley WS0000025232, para 67; MB/14 WS0000025712; AG/36 WS0000024438
250 AG/35 WS0000024435
251 AG/35 WS0000024435
252 Ellis WS0000027766, para 67
253 MB/17 WS0000025728
254 MB/18 WS0000025730
255 MB/19 WS0000025734; MB/20 WS0000025736
256 MB/21 WS0000025738
257 NE/21 WS0000028097

whether there were other factors the Trust would like to draw to the HCC's attention. No reply was received to this letter.

Healthcare Commission further analysis

9.238 The HCC began to scan mortality statistics proactively and as a result an alert relating to diabetes was generated. However, analysis disclosed that this was not an outlier when compared with nearby trusts, and the figures were therefore thought possibly due to primary care factors.[258]

9.239 On 7 November 2007, the panel considered two further internal alerts relating to epilepsy and abdominal aortic aneurysms.[259] The level of concern was increased because no reply had yet been received to the chasing letters in relation to the promised report, and it was noted that the Trust had come out as the fifth-worst trust in Dr Foster's Good Hospital Guide.

9.240 On 28 November, the panel considered a further alert generated by the DFU, this time on other circulatory diseases. However, on its own analysis, the panel did not consider this amounted to an outlier and no further action was taken. It appeared that coding was a potential explanation. It was agreed that all alerts should be reviewed at the next meeting.[260] The minutes of this meeting have not been found, but at some stage it was decided to hold a case conference specifically on the Trust.[261]

9.241 The case conference was held on 11 January 2008.[262] Again the minutes have not been found but the conference considered a report, which brought together information about the AHC ratings for 2005–2006 and 2006–2007, the medicines management assessment in October 2006, the children's service review of October 2006, performance star ratings, the inpatient and staff surveys for 2006, and the CHI clinical governance review of 2002. This appears to be the first time that an overview of this nature had been undertaken. In preparation for the meeting an analyst requested some up-to-date information from the DFU. The request referred to the HCC having had "growing concerns" about the number of mortality alerts.[263]

9.242 Nigel Ellis was asked whether the realisation of the serious implications of the mortality alerts should not have come sooner. He said that it was a cumulative process. In the beginning, the HCC had been satisfied by the Trust's responses, but as time went on:

258 Ellis WS0000027767, para 70
259 MB/25 WS0000025764
260 Ellis WS0000027768, paras 72–73; MB/26 WS0000025774
261 Bardsley WS0000025235, paras 76–77
262 Bardsley WS0000025235, para 77; MB/28 WS0000025791; Ellis WS0000027769; NE/25 WS0000028106
263 NE/23 WS0000028102

... one realises that we're, as you say, not receiving the responses that we were assured we would receive from the chief executive. As time goes on, we realise that this concern is much greater than when we started. And when towards the end of the year we look across all of these pieces of information, all of which are provisional, they are alerts, they're not failings in the quality of care. They are alerts which may represent failings. When we look across all of them together, and do further analysis, then we realised the extent of the problem. And it was for me a particularly important time when we undertook an analysis of the emergency cases together and realised just the extent of how much the trust was an outlier.[264]

9.243 He pointed out that there were some 85 alerts generated in total about various trusts, and in almost every case an innocent explanation had been found for apparent outliers. Against that background, and the early developmental stage reached in this form of analysis, the significance of at least some of those alerts concerning the Trust was difficult to detect.[265]

Referral to the Healthcare Commission investigation team

9.244 There is no direct evidence as to the outcome of the case conference, but on 14 January 2008, Nicola Hepworth, an HCC Investigation Officer, contacted Dr Rashmi Shukla of the WMSHA to say that the HCC was concerned about the number of mortality alerts for the Trust and that it was taking an interest in them.[266] The decision to refer the matter to the investigation team must therefore have been taken by then. Such a referral triggered what was called an "Initial Consideration", which involved obtaining and analysing information from the relevant Trust.[267]

9.245 On 28 January 2008, Dr Wood wrote to the Trust formally informing it that the HCC was considering the exercise of statutory powers and requesting various pieces of information. The letter stated that it was intended to visit the Trust in the near future.[268]

9.246 The letter was copied to the SHA but not to Monitor; Dr Wood explained that this was because she did not know that the Trust had applied for FT status.[269] Other bodies which were not notified of the increasing level of the HCC's concerns included the Postgraduate Medical Education and Training Board (PMETB) and the West Midlands Deanery.

9.247 The Trust's reply to the HCC's request for further information was not very encouraging. In an undated letter, Dr Suarez stated that the Trust had been actively working with the HCC regional assessors and had assumed this was the appropriate route for communication.[270]

264 Ellis T80.100
265 Ellis T80.110
266 Shukla T69.46; Buggins T74.134–5
267 Wood WS0000025047, paras 85–86
268 HW/3 WS0000025118
269 Wood WS0000025047, para 86
270 NE/29 WS0000028140

However, she promised that "all available information" would be transmitted to the HCC by 18 February, but that there were difficulties in tracing information as far back as January 2006 because of "organisational changes and loss of corporate memory". She stated that the Trust was "confident that [the documents sent] demonstrates that the Trust does not have higher than expected mortality rates."

9.248 The HCC appears to have discovered soon after the event that the Trust had been authorised by Monitor, and on 5 February 2008, Nicola Hepworth sent an email to Monitor informing of the start of the Initial Consideration in terms similar to that sent to the Trust earlier.[271] This information reached Monitor too late to be taken into account in its decision to authorise the Trust.

9.249 Dr Moyes said that Monitor was unaware of the HCC's planned investigation until a month after the Trust was authorised.[272] He stated that Monitor had contacted the HCC to notify it that the Trust's application was being considered but that there was no record of the initial contact being followed up. However, even if a further discussion had taken place his view was that it would not have made any difference given that the HCC regional officers were unaware that the investigation was being considered. Had he known that the HCC was considering an investigation of the Trust, he said:

> *... I have no doubt in my mind that Monitor's Board would have suspended the Trust's assessment. There were one or two cases in which the board suspended applications; until I signed a trust's authorisation, the process could be stopped.*[273]

9.250 In his evidence to the Inquiry, Dr Moyes remained firm that even if Monitor had received information about an HCC investigation just days prior to authorising the Trust, it would have been possible to pause the process.[274] He did accept that, with hindsight, Monitor should have taken more steps to ask the HCC whether it had concerns about the Trust during the assessment period.[275]

Report to the Investigations Committee

9.251 On 14 February 2008, Dr Wood placed a report before the HCC's Investigations Committee. It contained a summary of the concerns about mortality alerts. It appears that by this time the HCC had received a copy of the Trust's report on the jejunum alert, but Dr Wood stated that the HCC had not received satisfactory information in response to its requests. The Committee

271 HW/5 WS0000025126
272 Moyes WS0000039653, para 70
273 Moyes WS0000039706, para 221
274 Moyes T93.21–22
275 Moyes WS0000039707, para 225

decided that the concerns were sufficiently serious to warrant an investigation, but it was agreed that a final decision should be deferred until after the planned visit.[276]

Information from Cure the NHS

9.252 On 16 February 2008, the HCC received via its national helpline a collection of 40 letters and newspaper reports collated by Julie Bailey. It appears that this was entirely independent of the growing concerns at the HCC, but understandably it heightened these concerns.[277] The information sent by Julie Bailey would have contained the essence of many of the stories of appalling care which have so troubled both the first and the present inquiries.

9.253 According to Nigel Ellis, whether or not a decision to launch an investigation had already been taken on the basis of the mortality data, this information put the decision beyond doubt.[278]

Visits to the Trust

9.254 The HCC undertook unannounced visits to the Trust on 28 and 29 February 2008. What was found on these visits is well known, but various observations made by Dr Wood, who undertook the visits with two expert advisers (a consultant surgeon and a director of nursing), bear repeating here:

- Both A&E and the Emergency Assessment Unit (EAU) were poorly lit and badly laid out;
- In the EAU the inspectors found a lady on the point of falling out of bed who was not visible to the nurses on duty. They had to intervene. The number of nurses on duty was inadequate for the number and type of patients;
- On the medical wards the doors to several isolation bays had been left open, giving rise to an increased risk of spreading infection;
- A resuscitation trolley was found not to have been checked for a long time and had on it out-of-date injections and liquids;
- The team had general concerns about the adequacy of staffing.[279]

276 Ellis WS0000027774, para 95; NE/31 WS0000028149
277 Ellis WS0000027774, para 96
278 Ellis T80.107–108
279 Wood WS0000025049–50, paras 93–96

9.255 Dr Wood pointed out the importance of this sort of inspection for a regulator:

> *As well as checking technical/clinical issues such as the administration of intravenous fluids, fluid balance charts, resuscitation trolleys, cleanliness and infection control measures, inspectors need to observe staff on the wards, their appearance and professionalism. Effective observation and assessment are based largely on having the right experience, training and confidence i.e: knowing where to look and what to look for.*[280]

9.256 On 5 March 2008, the team returned to the Trust for a scheduled visit. On this occasion the Trust gave the team a presentation on its mortality figures, in which it was claimed that the results were attributable to coding. This did not satisfy the HCC team: "We did not accept this as the explanation and it could not answer some of our questions on the data."[281]

9.257 The team was also given cause for concern about the Trust's clinical governance. It found that in the Trust's own case note review of jejunum cases in September 2007, its reviewers had identified the case of a patient who had not received necessary cardiac medication for three days because of a "nil by mouth" order. They had required the case to be referred to the Trust's clinical governance committee. When the HCC team followed this up by talking to senior staff it became clear that the case had not been discussed by the committee and no action had been taken about it.[282]

Decision to investigate

9.258 The formal decision to launch an investigation followed soon after this visit. Draft terms of reference were shared with the WMSHA on 13 March 2008 and it was sent formal notification on 19 March 2008.[283] The public announcement, in the form of a press release, made it clear that the investigation had been triggered by the HCC's concerns at the Trust's monitoring of mortality rates, and the complaints which had by now been received from the public.

9.259 A period of five months had elapsed between the time the HCC received information about the first of the mortality alerts and the decision to undertake an Initial Consideration, and it took a further two months to conclude that an investigation was required. Nigel Ellis pointed out to the Inquiry that the HCC's own approach to analysing mortality rates was a very new creation and still in the process of development.[284] So far as the Dr Foster HSMR rating was concerned, both the Trust and the WMSHA appeared to be relatively unconcerned.

280 Wood WS0000025055, para 120
281 Wood WS0000025050, para 97
282 Wood WS0000025050–1, para 98
283 NE/32 WS0000028155
284 Ellis WS0000027776, para 105

9.260 Although Monitor was informed of this decision, neither PMETB nor the West Midlands Deanery was told directly, although the announcement was in the public domain. This resulted in the deanery only becoming aware of the serious training issues at the Trust when alerted to them by Dr Turner, an A&E doctor at the Trust, in the middle of 2009.[285]

Reaction of the Department of Health

9.261 It was inevitable that the DH was concerned at this investigation and its implications. However, its reaction and what it says about the relationship between the DH and regulators deserve scrutiny.

9.262 At the meeting in May 2008 between Sir David Nicholson and the HCC leadership, already referred to above, there was a discussion about the investigation.[286] Sir David is recorded as having expressed his "concern". He warned them about Cure the NHS:

> *David said there had been a local campaign group in existence against Mid Staffordshire for some time. Clearly patients needed to express their views but he hoped the Healthcare Commission would remain alive to something which was simply lobbying or a campaign as* [opposed][287] *to widespread concern.*[288]

9.263 This led Anna Walker, according to the note, to assure him that if this were the case, the investigators would recognise it. She further emphasised that the investigation had been triggered by a range of information about mortality outliers which did not of themselves "condemn" the Trust. She claimed that the level of cooperation from the Trust had been such that it had been difficult to reflect this positively in the press release announcing the investigation.

9.264 Sir David denied that he said anything at this meeting intended to suggest that patients or groups of patients should not be listened to, and he pointed out that this was not a note of the meeting he had approved and was not in his words.[289]

9.265 It was agreed that the HCC would keep the DH "closely in touch with developments on the Mid Staffordshire case".

9.266 As this was going beyond what was in the extant protocol for dealings with the DH, Ms Walker asked her team for advice on how this should be carried through. She said:

285 Hughes WS0000062178, paras 88–90
286 RD/1 WS0000035078–79
287 The actual word in the note is "proposed" but this is likely to be a typographical error.
288 DN/42 WS0000068498, page 1; Nicholson T127.183
289 Nicholson T127.183–184

I have no doubt that we should do more in the spirit of establishing a different relationship with David Nicholson and his team.[290]

Interim reports of investigation findings

9.267 The process of the investigation itself and its findings have been described in the HCC's own report, in the first inquiry report and in Dr Wood's evidence and do not require repetition here. However, it is of note that she distributed clear statements of concern arising out of the continuing investigation on a number of occasions, as itemised in the following paragaraphs:

Letter of 23 May 2008 and concerns about A&E

9.268 In a letter to Martin Yeates,[291] copied to SSPCT and the WMSHA (and Monitor and the DH), Dr Wood raised concerns about A&E, expressly as part of the HCC's policy "to raise any issues of concern regarding the safety of patients without delay".

9.269 It was accepted that the findings were provisional but also noted that they had been reached after consultation with senior specialist advisers who had taken part in the relevant visits. The concerns related to:

- Understaffing both in medical and nursing personnel;
- The structure and operation of the department, including lack of proper triage, patient mix in the Clinical Decisions Unit (CDU), inadequate monitoring and undue pressure on junior doctors;
- Lack of proper clinical governance to the point of there being "an almost complete lack of effective governance".

9.270 The cumulative effect of these matters was said to be that "the quality of care is compromised and that this constitutes a risk to the safety of patients".

9.271 As a result the HCC required these shortcomings to be addressed as a matter of urgency.

9.272 Sir David Nicholson was asked about this letter, which had been shared with the DH but not shown to him or Professor Sir Bruce Keogh at the DH at the time. He said that if he had seen it he would have referred it to the SHA as it was the responsible organisation locally. He would have assumed that, as the HCC was investigating, if it had thought action was necessary, it would have taken it either itself or in conjunction with Monitor. However, he would have wanted to know what action others were taking.[292] He accepted that the state of affairs revealed by the letter was not satisfactory so far as patient safety was concerned:

290 DN/42 WS0000068498, page 1
291 HW/6 WS0000025129
292 Nicholson T127.185–187

THE CHAIRMAN: ... Now, assuming for a moment that a response [to the letter] *is a favourable one, in the sense, "We accept what you say, we're setting about doing something about it", was not the system facing a trust, which had no effective governance, for whatever reason, a staff shortage in A&E and a risk to the safety of patients, which was only going to be begun to be addressed by a letter being sent before 3 June from the trust to the Healthcare Commission, is that a satisfactory state in which to leave the safety of the patients who after 23 May were continuing to visit that hospital?*

A. Clearly not.

THE CHAIRMAN: But what more does anyone require than the text of that letter to see that?

A. Well, as I say, if the Healthcare Commission wanted us to do something, they would have asked us directly to do it. Monitor were the right organisation to intervene at this particular stage if they wanted it. But my expectation was that Monitor would intervene on the back of this.[293]

9.273 He accepted that, had regular risk summits been in existence then as they are now, the reaction might have been different.[294] However, even at the time, "anyone who was in receipt of that letter I would have expected to take some action".[295]

Letter of 7 July 2007 – patients' complaints

9.274 This letter[296] was copied to SSPCT, the WMSHA, Monitor and the DH. It related to the concerns arising out of complaints from over 100 individuals raising serious issues about nursing care, dignity, hygiene, medication, failures of clinical care and communication which are by now all too familiar from the various reports that have preceded this one. Dr Wood noted that these complaints were consistent with the responses in the 2007 inpatient survey. Again, she accepted that the findings were provisional but pointed out that the messages from these individuals were consistent. She communicated to Mr Yeates a request that the Trust address any of these issues not already being addressed.

9.275 Bearing in mind that the HCC had become aware of the quantity and nature of patient and family complaints in February, Dr Wood was asked why this letter was not written much earlier. Her explanation was as follows:

293 Nicholson T127.191
294 Nicholson T127.192
295 Nicholson T127.193
296 HW/7 WS0000025136

I think that the chief executive of the trust was aware from a variety of sources of all of these concerns. I am happy enough to accept that perhaps we could have written the letter slightly earlier, but I think we might, had we written it immediately after April, been challenged on the basis of, "This is only information that you have from patients and relatives, what steps have you taken to check its authenticity?"[297]

9.276 Sir Bruce said that if he had seen the letter at the time, he liked to think that he would have contacted Professor Kennedy and Anna Walker "because it does pose questions as to whether enough was being done quickly enough".[298]

Press release of 25 September 2008

9.277 The HCC issued a press release about the progress of the investigation.[299] This stated that the Trust had responded "positively" to the HCC's concerns. It had increased medical and nursing staffing, but further recruitment was required to bring levels up to those recommended by the College of Emergency Medicine (whose recommendations were for four consultants against the 2.5 whole time equivalents at the Trust, and for nine middle-grade doctors against the eight in post now at the Trust) and to reduce reliance on temporary staff. The statement also said that the Trust had responded "rapidly" to the concerns expressed in May by developing an action plan. Nigel Ellis was quoted as saying that:

Clearly, in any investigation it is critical that matters that represent an immediate risk to patients are dealt with straight away. The trust has taken positive steps to bring staffing levels in A&E back to acceptable levels.

9.278 Mr Ellis was asked what the justification was for there being no intervention:

We reached the judgement that the situation was very serious but the improvements that were required, once we had received information back from the Trust, that there was an action plan in hand and that we did not require the Secretary of State to take any additional action. I mean, we are focused on getting the problem resolved as quickly and as practically as possible. If we had felt that there was any need for the Secretary of State to take additional or other action, we would have recommended special measures ...[300]

Letter of 15 October 2008 – continuing concerns

9.279 This letter,[301] copied as before, pointed to key areas of continuing concern where Dr Wood thought the Trust should focus its attention in improving services. These included staffing; the

297 Wood T81.116
298 Keogh T123.44
299 BK/17 WS0000065553
300 Ellis T80.159
301 HW/8 WS0000025138

skill mix in, and operation of, the EAU; the care of traumatically injured patients; surgical out-of-hours cover; and lack of protocols for unscheduled care.

9.280 Taken together or separately, these letters suggest that the investigation team had come to conclusions, properly based on evidence, that there were persisting areas of serious concern relevant to patient safety. It is impossible not to read into these letters an opinion that patient safety was at risk in more than one area of the hospital. In dealing with the question of the HCC's response to what was agreed to be "blatantly obviously ... unsatisfactory" with regard to the situation in A&E, Dr Wood described a position whereby she had raised the matter with the Trust but felt a tension between the need to act quickly and the need to evaluate material properly and not rush to conclusions.[302] She felt that despite the situation that had been found in A&E in May 2008, where "serious concerns" about the safety of patients had been unearthed, the value of closing the department was outweighed by what was seen to be the greater harm that closure would cause to patients.[303] Nigel Ellis said that although the situation was "very serious" and that improvements were required, once it had received information from the Trust that there was an action plan in hand, it did not at that stage require any further action to be taken by way of special measures.[304]

9.281 Further, on receipt of the third letter of concern from the HCC to the Trust Dr Moyes wrote directly to the Trust on 21 October 2008, requesting a copy of any response that the Trust was to send to HCC, as well as any related action plans.[305] The letter also requested the date by which the Trust planned to meet the A&E target. Martin Yeates responded on 22 October, agreeing to respond by 5 November 2008.[306] Monitor received a response from the Trust on 3 November 2008.[307]

Interaction with Monitor and the Strategic Health Authority about the length of the investigation

9.282 From the beginning of the investigation, the HCC kept Monitor informed of developments. Monitor for its part expressed concerns about the nature of the investigation and the time it was taking.

Meeting on 3 June 2008

9.283 At a meeting between Dr Wood, Nigel Ellis of the HCC and four officials from Monitor, the HCC pointed out that it was unusual, but not unheard of, for it to have written to a trust in the course of an investigation setting out serious patient safety concerns over A&E.[308] Mr Ellis

302 Wood T81.117–118
303 Wood T81.109–110
304 Ellis T80.159
305 YM/31 WS0000040984
306 WM/33 MON00030000370
307 WM/36 MON00030000485
308 HW/9 WS0000025145

explained that if the HCC was happy with the Trust's response it would continue the investigation and then look for assurance that action plans were being implemented effectively. If it was not satisfied with the Trust's response it would consider the need for external intervention. There ensued a debate about whether intervention should be by the WMSHA – to which Monitor objected – or Monitor.

9.284 Dr Wood warned Monitor that it was likely she would be writing to the Trust in the near future about medication management.

Meeting between Dr Moyes and Anna Walker – July 2008

9.285 At a meeting in July,[309] Dr Moyes suggested to Anna Walker that the HCC end the collection of evidence and "place more emphasis on sorting out the problems". Following this in an email, it was reported that Dr Wood had expressed concerns to Monitor officials about "coming to a conclusion before they had all the evidence."[310]

9.286 It was, however, also recorded that Dr Wood had said that the Trust was taking the issues raised seriously and was trying to put them right. Dr Moyes' view, as expressed internally at the time, was:

> *I'd like to persuade the HCC that enough evidence exists and that the focus should no longer be on establishing a watertight case – if we wanted to there is, I suspect, enough to allow us to intervene – but on getting change. I don't think enough thought is going into the challenges required to secure lasting improvement. The HCC have highlighted staffing issues, dignity of care issues, training requirements. What we don't know is whether the existing board, management team and clinical leadership can or cannot deliver permanent changes on the scale required. We also don't know whether the HCC's work is raising questions about the validity of some of the FT's clinical services eg A&E in its present form and therefore whether short-term fixes might not be the best response from the FT.*[311]

Dr Moyes' letter of 15 September 2008

9.287 Dr Moyes wrote to Anna Walker stating he was "keen" to use Monitor's intervention powers to ensure effective action at the Trust. He believed this was urgently needed to achieve a well-governed trust, delivering high-quality care. He was concerned at the time being taken:

309 NE/49 WS0000028262
310 NE/49 WS0000028262
311 NE/49 WS0000028262

My principal concern remains the diminishing benefits of continuing the current programme of investigation ... An ongoing investigation (over a period of twelve months by the time it is completed) risks tying up senior management's time in addressing detailed operational matters and responding on a reactive basis to your specific findings.

The resulting actions may or may not be in the longer term interests of the Trust or its patients, or compatible with the developing requirements of its main commissioners. A further cost of this reactive approach is that the Trust's senior management has little capacity and time for effective consideration of the forward thinking strategic changes which the Trust should be making ...

We believe it would be in everyone's interests for the HCC to complete its investigation as soon as possible (while ensuring that the main concerns from the investigation have been identified and addressed).[312]

Anna Walker's position – October 2008

9.288 In her reply to Dr Moyes on 6 October 2008, Anna Walker defended the HCC's position and made it clear that it intended to pursue the investigation because its findings to date were provisional and it was not in a position to set out the broader actions required.[313] She said that matters thought to "pose an immediate threat to the safety of patients" had been reported to the Trust but other judgements remained to be made. One of these concerned the emergency care pathway, which may still have been posing a risk to patients.

Telephone call with the West Midland Strategic Health Authority – October 2008

9.289 In a telephone call with Ms Walker in October 2008, Peter Shanahan of the WMSHA criticised the conduct of the investigation by Dr Wood. In particular, he was concerned at the length of time it was taking, as it was "dragging down" the Trust's reputation. Ms Walker responded that although she understood his concerns, the quality of the investigation was more important than the exact time it finished.[314]

Publication of the report

9.290 Draft extracts of the report were shared with various stakeholders for fact-checking and comment, but not the full report. This resulted in a highly critical reaction from the WMSHA. This included an allegation that the HCC was "data dredging", ie finding data to fit a preconceived hypothesis. Monitor, too, objected that the evidence referred to in some extracts it saw did not support the conclusions. In both cases, having seen the full report, both bodies accepted before the Inquiry that these criticisms were not correct.

312 HW/9 WS0000025147
313 AW/38 WS0000030019
314 AG/70 WS000002468

9.291 In the final stages of the preparation of the report the full draft was shared with senior DH officials, the Secretary of State for Health and the Minister of Health, and high-level discussions took place about it. In particular, there was a discussion over whether a reference in the report to a number of "excess deaths" should be removed. The Inquiry heard detailed evidence from many of those involved. It would be disproportionate to recite all this evidence here as it is all now in the public domain, but in the end it was clear that the decision to remove these figures from the report was Professor Sir Ian Kennedy's and that he was not placed under any political or departmental pressure to take this step.

The Healthcare Commission's justification of the length of the investigation

9.292 In evidence, the HCC witnesses maintained the position taken in their correspondence and meetings with Monitor and the WMSHA.

9.293 Dr Wood pointed out that although Dr Moyes had been critical of the length of the investigation while it was going on, he suggested at the end that there was insufficient evidence to support some of the findings.[315]

9.294 Nigel Ellis did not consider Dr Moyes justified in his criticism:

> *I do not believe that terminating that early on would have been to the interests of the public, and I do not believe that I would have been – that we would have been able to deliver a robust investigation. So I don't share the view that there were diminishing benefits at an early stage, and I don't quite understand how that conclusion could be arrived at, if you don't have access to the evidence.*[316]

9.295 However, he understood the sense of frustration at the length of time being taken:

> *The prize was always, in my view, worth the time. We needed to have a robust, clear and full investigation report. So we believed that it was worth the time. It was necessary to – to spend this time. But, yes, I understand why somebody might have been frustrated in the situation that he was in, that he wanted this to be over sooner than it was. But I think that that was understood by us and shared by us as well ...*
>
> *I think that there's every chance if we'd have stopped the investigation early and not completed it fully, that these lessons would not have been learnt. I think that's very likely.*[317]

9.296 He felt that a "very strong message" was coming from other organisations that it should stop the investigation:

315 Wood T81.117–118
316 Ellis T80.129
317 Ellis T80.131

What I did see, throughout the investigation, was a very strong message given to us, that we should desist and that we should stop at an earlier point, which I simply don't agree was the right thing to do.[318]

9.297 Nigel Ellis also described learning of an email from Martin Yeates to Peter Blythin at the WMSHA in August 2008, disclosing in confidence information concerning one of the HCC requests for information from the Trust. In this email Martin Yeates expressed concern at the level of scrutiny by HCC. Nigel Ellis felt that this email suggested a level of familiarity between the Trust and the WMSHA that was not appropriate.[319]

9.298 Peter Shanahan of the WMSHA also voiced his concerns over the length of time the investigation took: "For me the most worrying issue about the HCC review process is that it took 14 months from when the HCC went into the Trust until they produced their report."[320]

9.299 Anna Walker maintained that although the report was not published until March 2009, action was being taken both by the Trust and by Monitor:

THE CHAIRMAN: But if an investigation is to last, as this one was predicated to last, about 12 months, it can't be right, can it, for there to be a sort of institutional paralysis while that takes place, because patients are still being treated and have a proper concern about safety?

A. Absolutely, and indeed there wasn't an institutional paralysis in this case, because actually two things, first of all, the Healthcare Commission, the investigations team did take some action when the concerns over A&E became clear, and actually Monitor was also, by then, beginning to look at those issues in-depth as well. So they were, even if they weren't carrying out concrete action and actually exactly what they did, I am not clear, and it's clearly for them to answer, they were very involved with the issues and taking a view on what lay behind the issues and what needed to be done, and that I know from my conversations with Bill Moyes.[321]

Explanations for the absence of intervention during the investigation

9.300 The position taken by HCC witnesses, as reflected in the quotation above from the evidence of Dr Wood, was that stakeholders were kept informed about provisional findings throughout the investigation and that therefore it was for them to intervene in accordance with their responsibilities if they thought it was necessary. The position of others was that they were entitled to assume that the HCC would seek an intervention if that was necessary and that the HCC did not suggest that the situation was sufficiently serious to warrant that.

318 Ellis T80.132
319 Ellis WS0000027781–2, paras 126–128; NE/51 WS0000028269
320 Shanahan WS0000020520, para 91
321 A Walker T83.167

9.301 Sir David Nicholson thought that it would have been very difficult to take action before the conclusion of the Inquiry:

> *Q:* [referring to the report of the first inquiry] *It's fair to say that there are also reports of good things which had happened to the trust but by and large, as you will be aware, there is a litany of complaints of, frankly, on occasions dreadful things happening in terms of care. Do you think, now, that either the Department itself or Monitor or indeed the SHA should have intervened much more actively and much sooner, rather than allow the HCC investigation to wend its careful but rather slow course?*
>
> *A. I think it is very difficult to think back to all of that. I mean, my assessment of all of this is that the Healthcare Commission were in there, they had people on the ground. I do not believe that Healthcare Commission investigators walk around with clipboards making comments about problems without directly bringing them to people's notice and intervening if they need to and bringing in the right people that they need to when they are doing their work. I think it's perfectly reasonable to have expected them to do that ...*
>
> *... And if you've tried to intervene before a report with its recommendation and conclusions have come out, it's always very difficult, isn't it? ...*
>
> *... what I'm saying is that if the Healthcare Commission believed that there were things wrong and the trust were not putting them in place, then they should have – they should have spoke to Monitor and Monitor should have intervened directly. That was the way the system is supposed to work.*[322]

9.302 Professor Sir Bruce Keogh, who, like Sir David, had not seen the letters from the HCC expressing concerns at the time, offered his thoughts retrospectively on the need for intervention:

> *We had the Healthcare Commission, an independent regulator, independent from the Department of Health and independent from any other organisations in the healthcare system. We had a primary care trust, whose job it was to commission services and who had a duty to commission good services from the trust. And we had a performance manager in the form of the SHA. So in the light of also getting assurances from the Healthcare Commission, and you've seen those assurances, and they're attached as my exhibits, that at numerous points in this chain where I and others asked the Healthcare Commission, "Is any intervention required?", the answer was always "No", because there was an expectation that things were improving.*[323]

322 Nicholson T127.188–190
323 Keogh T123.49

Conclusions

Key recommendations of the Bristol Inquiry have not been followed

9.303 In his evidence to the Inquiry Professor Sir Ian Kennedy said that having considered the recommendations of his inquiry in the light of the experience at the Trust, he would not wish to change them:

> *Overall my view is that an independent regulator is key, and regulation that has safety, quality and standards at its core, must be co-ordinated and aligned, to ensure that roles and responsibilities are clear. This avoids both gaps and duplication, Most importantly, patients should be at the centre.*[324]

9.304 Instead of aligning systems and regulators under one genuinely independent umbrella organisation, first the HCC and then the CQC were set up. Neither became an overarching organisation of the type envisaged by Professor Kennedy. Indeed a further regulator was added, Monitor, which defended its territory in the way the Bristol report sought to avoid. NICE has continued with conspicuous success to formulate clinical guidelines that are incorporated by reference into commissioning contracts and standards, but it remains a free-standing organisation that is not part of the regulatory system.

9.305 Generic standards were formulated not by the regulator but by the Government, thus inhibiting the independence of the regulator (see below).

9.306 To this day, the boards of regulators are hired and fired by the Secretary of State for Health.

9.307 Professor Kennedy laid emphasis on safety being the fundamental prerequisite of good patient care. It was on that basis that further improvements of quality could be built. While the importance of safety has been recognised in the various iterations of standards since then, it has been intermingled with quality considerations to such an extent that its importance may have become unintentionally downplayed.

9.308 Above all, the importance of the clarity of responsibilities, with alignment to avoid duplication and gaps, has been demonstrated again by the failure of the system. As Professor Kennedy would call it, the "plethora" of theoretically responsible agencies failed to detect the deficiencies and their gravity at Stafford in time to save many patients from horrific and tragic experiences.

324 Kennedy WS0000025839, para 11

Status of the Healthcare Commission

9.309 Professor Kennedy had recommended in his Bristol Inquiry report that the regulator be independent of the DH. In practice, there appear to have been constraints on the extent of its independence that were not helpful to the performance of its role.

Creation of core standards

9.310 While there was a consultation period, the fact is that the standards were formulated and handed down by the DH. Concerns expressed by Professor Kennedy and others were communicated and considered but largely rejected. While the manner of assessing compliance was left to the HCC, this process must have contributed to the impression that the creation of the standards was controlled by the Government and thereby reinforced the disengagement of front-line clinicians from a concept, which if it were to work, demanded their involvement and endorsement. Standards which are handed down by Government, even after a from of consultation, are likely to be interpreted, rightly or wrongly, as serving political ends rather than the interests of the patients they are intended to protect, unless they are seen to be fully informed by public and professional opinion. There was likely to be confusion between targets and standards, between the minimum acceptable standard and what was regarded as desirable, but perhaps, more discretionary improvement.

9.311 It was perhaps inevitable that in the first instance the new concept of setting national standards would remain under the close control of Government. Mr Bradshaw set out eloquent arguments as to why this should be so. The move to setting standards at all was a progressive development, designed to promote the protection of patients and make improvements to the service. The experience of such an approach suggests, however, a need to change, and for the setting of fundamental standards, at least, to be left more transparently to a genuinely independent regulator, leaving requirements for improvement to the commissioning system, for which, ultimately, the Government can be held to account via its use of the "mandate". The combination of a "top-down" promulgation of standards covering both areas (core standards and developmental standards), and the delegation of regulation of these to a regulator, was likely to weaken the regulatory focus on ensuring core standards were observed, while at the same time reducing the responsibility and accountability of both local bodies and the DH for achieving desirable improvements.

Attitude to investigation and the desire to be kept informed

9.312 The initial attitude of the DH to the investigation was understandably one of concern. The proper desire of Ministers and senior officials in such circumstances to be kept informed needs to be more tempered and informed by the need to avoid any impression that they are seeking to interfere with the conduct of the investigation or the judgements being made by the regulator.

9.313 Sir David Nicholson's suggestions about CURE in May 2008, if expressed as recorded in Anna Walker's note, would have been inappropriate. However, Sir David has denied that he would have said this or intended to convey such a sentiment, and this Inquiry accepts that whatever he was understood to have been saying he had no intention to convey any disapproval of CURE or suggestion to the HCC as to how it should approach this group. Ms Walker, although believing the comments had been made, rejected the suggestion they had been made in an attempt to influence the investigation. It is not possible to determine at this distance in time what precisely was said, but the incident is at least illustrative of the care that needs to be taken at this sort of meeting to avoid the impression that the DH is seeking to influence an independent regulator as to how it should conduct specific regulatory activity. It is not suggested, however, that every contact between regulators or between regulators and the DH should be formally and fully minuted. Although there should be some note made of all such contact, it is recognised that open communication with and between regulators for the purpose of exchanging information and, where appropriate, coordination of action is an important facet of the system.

9.314 It would not have been appropriate to put the HCC in a position of having to justify its actions at this time. Investigations and inquiries are made much more difficult if those conducting them have to provide a running commentary on what they are doing, except at times and in a manner which they, the investigators, consider appropriate and in the public interest.

Regulation of commissioning

9.315 The resistance within the DH to the concept of the regulation of commissioning may have contributed to a lack of clarity about the requirements of regulation in this field. This would in part at least have been due to the novelty of the concept.

9.316 It may also be suggested that regulating commissioning and the actual provision of services together breeds a degree of confusion about what regulation in healthcare is intended to achieve. It reinforces the concept that the regulator is a Government agent whose purpose is to advance Government policy, rather than one whose priority is the protection of patients and the maintenance of standards. It blurs the distinction between standards of safety and quality, and the commissioner-led targets, aspirations and scoping of the provision. A process that requires the regulator not only to monitor compliance with standards by a provider trust but also the oversight of the same standards by the commissioner carries a level of unnecessary duplication. Commissioners were and will be accountable to the public, although the means of accountability have changed under the recent reforms. Their role is to define the services required to serve the public, for which they are responsible, and which it is appropriate to commission within the resources allocated, to ensure that those services are made available; and to set and monitor standards and, if necessary, targets, which they expect to be achieved. A regulator is likely to be more effective and more easily understood if

its focus is on the provider. Therefore, albeit for slightly different reasons, the evidence to this Inquiry leads to sympathy with the reservations Sir David Nicholson harboured on this issue.

The Healthcare Commission regulatory management of the Trust before the investigation

9.317 It is clear that the AHC was not a satisfactory means of establishing whether the Trust or any other provider was complying with satisfactory standards of care, but this was not the only means by which the safety and quality of the Trust's service could be assessed, and there were warning signs which could have triggered a greater level of concern sooner. It is not intended in what follows to attribute responsibility or to criticise any individual HCC official, as it is much easier to see the need for action in hindsight than it was at the time. However, taken cumulatively these areas of concern should have triggered an earlier regulatory response and more proactive intervention than in fact occurred. In some cases, the individual issues raised carried wider implications for patient safety than were actually explored. What is shown by the HCC's early dealings with the Trust is the adoption of a system highly unlikely to uncover systemic weaknesses at an early enough stage to prevent serious harm to patients.

Complaint about hygiene – 2006

9.318 While this complaint may not of itself have required further action at the time, particularly in view of Ms Hawkins' assessment from attending a PPIF meeting that the situation had improved, there is no evidence that issue remained visible in subsequent HCC assessments of the Trust to ensure that concerns of a similar nature were not occurring.

Concerns about appraisals – 2006

9.319 An organisation that was not conducting appraisals effectively was potentially failing to capture issues of concern about its professional staff. The HCC obtained information that suggested appraisals were not being conducted effectively at the Trust and this was appropriately logged in the HCC's information systems. Such information, if considered to be reliable, should not only be logged but followed up, rather than merely forming part of the background for future assessments. There is no evidence that this occurred. The fact that appraisals were not being conducted effectively in a number of trusts was not a reason for failing to address the issue.

Healthcare Commission reviews of children's services – 2006

9.320 A number of concerns should have been apparent from the Trust's handling of this review:

- The failure to submit the necessary documentation raised questions about the general governance of the Trust and its ability to handle and use important information.
- While a degree of hyperbole is to be allowed for, to be told by an auditor that governance was "non-existent" should have raised serious alarm bells.

- The apparent failure of management to have explained to senior clinical staff before the improvement workshop why the Trust's rating was weak indicated that there might have been a systemic failure of engagement of clinicians in governance, as indeed proved to be the case.
- The Trust's tolerance of a lack of formal life support qualification in the children's service should have raised serious questions about the Trust's attitude towards patient safety.
- The HCC was indeed aware of these issues and was not inactive, as described above. However, the Trust's assurances that staff in fact had the necessary experience, if not the PALS training, that action plans would be prepared and implemented, together with changes in leadership at around the same time, were accepted too readily as evidence that these concerning issues were being addressed in areas where patient safety could have been at risk at any time. It was wholly unacceptable, after having found that necessary training was not in place, to proceed on the basis that, since there had been no patient deaths, there was no evidence of harm. That was setting the level of acceptable risk far too high. As it happened, the HCC's investigation does not appear to have found a continuing deficiency in this regard, but this does not diminish the fact that inadequate weight was given at the time of the review to the continuing risk to children.

9.321 Clearly the HCC would have been more likely to react in this way had it been aware of the outcome of the West Midlands Children's Service Peer Review, but it was not. This is one of the many examples that came to light over the course of this Inquiry of important information, relevant to patient safety, not being shared with those organisations with a responsibility for protecting patients.

9.322 It has been suggested that the failure to take action might have been the result of "regulatory capture" of the regional team, but it is more likely that the cause was the system, which, both locally and nationally, discouraged intervention by emphasis on the Hampton principles of proportionality and risk-based inspection (as discussed above) and required information to be logged centrally. Insufficient weight was given to the risk to patients arising from individual items, which, when examined, were in themselves cause for concern. All this was set against a background that placed considerable reliance on assurances from trusts as to remedial action, as opposed to some form of inspection, to find out, for example, whether trained staff were in fact in place when children were being cared for.

Potential inconsistency between the Annual Health Check self-declaration and the Trust's own information

9.323 The HCC was aware through Ms Hawkins' engagement form in mid 2006 that an auditor was concerned that the Trust's self-declaration was, in important respects, inaccurate.

9.324 This should have raised the question then and there of whether the Trust's self-assessment could be relied on at all. However, again, the HCC, at local level, accepted assurances that

improvements were being made. Even if these assurances were genuinely and honestly intended by Trust leadership, and they probably were, this information should have led the HCC to take a very close and urgent look at whether patient safety was being compromised. If self-declaration was to mean anything at all, then the filing of inaccurate information should have been regarded as a very serious deficiency. Merely to accept that something was being done to correct this failed to recognise that a failure had occurred for which the Trust needed to be held to account. It would be wrong to allocate responsibility for this to Ms Hawkins. As a local official she had performed her duty by reporting the information. There is no evidence that she was then required by those higher up in the system to take any further action, or that anything else was done until the information was used to inform the core standards risk-based assessment the following year. However, as has been seen, this inspection did not identify that the declaration for the previous year had been inaccurate.

Concerns about resuscitation equipment – 2006

9.325 It might have been thought that the governance concerns rightly thought by Ms Hawkins to be raised by her findings during her BPAS inspection in September 2006 were part of a consistent and concerning pattern taking account of the training and governance issues raised earlier in the year.

Annual Health Check declaration for 2006–2007

9.326 The Trust's declaration of substantial compliance with the core standards was not universally accepted by the stakeholders who commented on it. The HCC's cross-checking in accordance with its system revealed a substantial number of indicators on which the Trust performance was rated as "worse" or "much worse than expected", in particular the mortality analyses of various diagnostic groups conducted by the HCC, and the concerns raised about governance.

9.327 Sufficient concern was raised to trigger a risk-based review, which took place in July 2007.[325] This was entirely focused on examining paper evidence; the examination was intended to show that the Trust had a system in place, to see if evidence of outcomes was passed through the system and to examine how that was able to assure the Trust the system was effective.[326] There was no physical inspection to see if practice on the ground matched up with the paper evidence. A limited number of reports of other agencies were also looked at. The HCC accepts that this inspection failed to identify the serious flaws in the Trust's governance structure that were later uncovered in its investigation.[327]

9.328 No inquiry was made about mortality rates or their implications even though mortality was one of the issues which triggered the review. By the time of this assessment, Dr Foster mortality figures had been published, relating to the year under review by the HCC, but these

325 Hawkins T78.122
326 Cleary T95.67–68; Hawkins WS0000026358, para 82; Hawkins T78.100–103
327 CL0000001591, *The HCC closing submissions*, para 131

were not taken into account. It was not until a little after this review that the HCC was able to use its newly developed mortality outliers programme to identify the Trust as an outlier.

9.329 It is of particular concern that the favourable outcome for the Trust in this assessment for 2006/07 meant that the negative indicators present on the HCC database were to be accorded less weight in the following year. Therefore, for the purpose of the AHC for 2007–2008, the potential warning effect of cumulative negative information was removed by reliance on a core standards assessment, which relied on an inspection of documentation that had not highlighted the serious issues at the Trust. Completely absent from this assessment in 2007 was any form of independent judgement of whether the Trust was actually delivering the quality of service to its patients that its policy suggested it ought to have been.

Hygiene code inspection – 2007

9.330 The HCC is disadvantaged by not being able to locate the full report prepared by Ms Hawkins following her inspection in January 2007. It must also be recognised that the hygiene code was a new and positive development in the battle against hospital acquired infection and that this was a pilot visit. Nonetheless, the summary report, prepared in language that has become all too familiar at this Inquiry, and is prevalent throughout the system, shows an almost entirely useless regulatory process in action. The "inspection" did not involve any form of visual observation of actual conditions in areas where patients were cared for, or tests for the presence of dirt, germs or other indications of poor hygiene practice. Whatever may have been in the now untraceable full report, the summary version focused on whether the Trust could produce policy documents, demonstrate its directors' familiarity with these and the existence of Board reports. The report contained no consideration of the actual content of any such Board reports, or of the extent to which HCAIs were actually prevalent in the Trust.

9.331 Ms Hawkins herself in the evidence quoted above exemplified once again the HCC's willingness to accept assurances of action from the Trust at face value. Regulation cannot be effective if it does not challenge claims of compliance made by the regulated organisations, and its prime purpose in protecting patients cannot be served by such a passive approach.

9.332 It would be easy to offer criticism of individuals in relation to the failure to investigate more intrusively concerns being expressed about hygiene at the Trust. However, the acceptance by the HCC of the report described shows that the management of the issue by the local team was what was expected of it. The fault therefore lay in the inadequacy of the system in place to pursue a potentially serious concern effectively.

Risk summits

9.333 The arrangement of risk summit meetings was a very positive step in improving the collaboration and coordination between regulators and performance managers. Given the plethora of organisations responsible for various, often overlapping, aspects of healthcare

oversight and regulation, such communication was, and remains, absolutely essential. Any such arrangements are bound to take time to mature, particularly where no operational and systemic provision is made for them prior to the creation of new organisations, in this case the HCC and Monitor. Therefore, it would be wrong to criticise such an early meeting as that which took place in February 2007 for its apparent superficiality.[328] Nonetheless, it is worthy of note that at this stage HCC did not have on its radar the rather wider concerns raising practical risks which have been described both in this chapter and in *Chapter 1: Warning signs*.

9.334 The meeting represented a lost opportunity for the HCC to be made aware of the West Midlands peer review of children's services. This may in the first instance have been because the WMSHA did not send anyone to the meeting, but as the SHA would have received a copy of the minutes, no one there seems to have thought it might be helpful for the HCC to be informed of this.

9.335 Communication of intelligence between regulators needs to go further than sharing existing concerns identified as risks, but should extend to all intelligence that, when pieced together with that possessed by partner organisations, may raise the level of concern. Clearly, it may be difficult to identify the appropriate level of information that should be shared. A balance has to be struck between ensuring that all potentially useful information is shared and overwhelming organisations with detail, thereby allowing important points to be lost. As always there has to be a degree of judgement involved, but there is no doubt work could be done on a template of the sort of information each organisation would find helpful.

Complaints handling by the Healthcare Commission

9.336 The HCC was handicapped by the manner in which the duty of handling second-stage complaints was imposed on it, the unacceptable delays in the passage of the regulatory framework and the underestimates in the workload involved. It is therefore not surprising that there were delays.

9.337 The stories involved in the 12 complaints that originated from the Trust's patients show the convoluted process to which they were subjected and of which the HCC was but a part. The many stories told by patients and their families to both this and the first inquiry shows how poor handling of their complaints can compound any suffering and sense of bereavement caused by the deficiency in service that led to the complaint in the first place. Even where complaints are justifiably not upheld, serious suffering can be caused by the way the matter is handled.

328 AG/20 WS0000024267

9.338 The crucial elements of a good complaints service are:

- Easy access to a complaints process: concerns can be raised in many forms, but whatever the method, however it is expressed, if it amounts to a complaint it should be dealt with as such, unless the person expressing the concern expressly refuses to allow this, in which case the matter should be considered as an incident;
- Early identification with complainants of what they expect from the process and what can be delivered;
- Prompt processing: responses, information collection, analysis and determination should all be completed within a proportionate time;
- Thoroughness: all issues raised by a complaint, whether or not expressly articulated by the complainant, should be addressed;
- Sensitive, responsive and accurate communication: complainants do not want formulaic, template letters, but evidence of genuine, thorough and open-minded consideration of what has troubled them through the best means of communication for the individual;
- Learning from complaints must be effectively identified, disseminated and implemented. The achievement of this should be demonstrated to the complainant and the public.

9.339 Obviously, by the time a complaint reaches a second stage irretrievable damage may have been done. Unfortunately it is likely that the problems associated with the HCC process compounded any suffering caused by defects in the initial process.

The decision to investigate

9.340 The Dr Foster HSMR seems to have played little or no part in raising the HCC's level of concern about the Trust, although it would have been aware of it. The explanation appears to be that it was satisfied by the assurances being given out by the Trust, including, presumably, its presentation on mortality in November 2007, and the reaction of the WMSHA, which was largely to accept the Trust's interpretation that this was a coding issue, and that what was required was an analysis of the reliability of the data and the HSMR methodology.

9.341 While a regulator should be proportionate and fair in its approach to intervention, it appears that the HCC, like so many other bodies at the time, was distracted from the true significance of the HSMR. This was not that it showed that avoidable deaths were definitely occurring, but that it highlighted a risk of that being so that required consideration. While criticisms were made widely about HSMR methodology, it had been deployed by a reputable source and, whatever its weaknesses, it was at the time one of the only tools available for considering mortality relevant to patient safety.

9.342 A more positive reaction to the HSMR at the time could have led the HCC to make more searching inquiries, of the type begun in December several months earlier. These would have revealed the sorts of concerns Dr Wood and her colleagues uncovered in February.

9.343 The HCC was not, of course, alone in failing to act on the HSMRs, and in an atmosphere where intrusive regulatory intervention was not to be embarked upon lightly, it is understandable that at the time it required a firmer basis on which to act. It is therefore to its credit that the HCC set about developing its own methods of analysis of mortality, focusing on a more useful – from a regulatory point of view – and granular approach, and in its liaison with the DFU to use the DFU's alerts.

9.344 A degree of hesitancy in acting on the concerning accumulation of alerts for the Trust was understandable, bearing in mind the novelty of the HCC's methodology and the wide confidence intervals associated with some of the alerts. However, there was an inconsistency between its willingness to use them as a basis for requiring information from the Trust using its statutory powers[329] and the HCC's hesitation in reacting to the failure of the Trust to give a satisfactory response. If the data in the HCC's possession was good enough for one purpose then logically it was good enough for the other. The point that should always be remembered about this sort of mortality analysis is that it does not prove there has been a poor service, but is an indication of the need for further enquiry. It is only by such enquiries and by an examination of the actual service that has been, and is being, delivered that the true picture is going to emerge. Unless that is done, the regulator and the public are not in a position to know whether there has indeed been failure to comply with standards leading to death and morbidity. It is a prime duty of a healthcare regulator to assess and protect patients and the public from risks of serious harm, as well as to call providers to account for harm that has already been caused. Nonetheless, it is clearly much easier to make this particular judgement in hindsight than it would have been at the time.

Conduct of the investigation

Length of time

9.345 The HCC was subjected to a great deal of pressure from Monitor and the WMSHA about the length of time taken for the investigation to report. This criticism was and remains ill-founded. It is quite clear that Dr Wood and her team found an unprecedented range of issues suggestive of serious concerns. If they had acted as suggested, in particular by Dr Moyes, it is highly unlikely that the full breadth and gravity of the issues would have been brought to light. It would have been much easier for the Trust, and the wider system, to have perpetuated the Trust's by-then habitual response to concerns and complaints of assuring all and sundry that there were action plans in place which were being implemented. The HCC was absolutely right to insist on undertaking a thorough and searching investigation and to take the time necessary to do that. Obviously, investigations are unsettling and distracting for those subjected to them. That is no reason not to conduct them when justified, as was the case here.

329 Ellis T80.114

9.346 What is required is not a short-circuiting of the investigation, but the introduction of adequate interim mechanisms to protect patients and the public from any risks caused by it. If, for example, it is feared that management are being distracted, then further support may be required to be offered.

9.347 The principal argument, put forward by Dr Moyes in particular, was that the continuance of the investigation prevented action being taken to remedy the concerns and address the longer-term strategy required. This would have been a serious consideration if it were justified, but it was not. Monitor's own internal correspondence reveals that Dr Moyes thought that there was probably already sufficient grounds for intervention if that is what was decided. Monitor decided not to do so and that judgement will be examined elsewhere. However, there was nothing intrinsic to an HCC investigation that suspended the statutory powers or responsibilities of Monitor or indeed the commissioners or other bodies.

Level of intervention during the investigation

9.348 The HCC was hampered by having no powers of its own to intervene to require corrective measures to be taken. It had to act by way of recommendation and reporting to other organisations, while at the same time not appearing to prejudge issues before a final determination of them. It was theoretically open to legal challenge should it step outside its powers and its public law duties. The investigation team did on several occasions draw concerns relevant to patient safety to the attention of Monitor, SSPCT, the WMSHA and the DH, all of which had powers of one sort or another to require problems to be addressed: in Monitor's case, it could have exercised its powers to issue directions to the Trust Board, or to remove directors. In the case of the PCT and the performance management structure above it, action could have been taken under the terms of the commissioning arrangements.

9.349 In spite of the extremely serious situation that was being uncovered by the HCC investigation, none of these organisations took such action, but limited themselves to obtaining assurances from the increasingly beleaguered and defensive Trust leadership that action was being taken. In the case of Monitor, it is clear that towards the end of the process its leadership was giving serious consideration to intervention, but the general approach of all was to await the final report of the investigation before taking substantive action. This stance was not obviously opposed by the HCC, and indeed the positive tone of the press release issued in October 2008 might reasonably be thought to have offered a degree of assurance that patient safety was not compromised.

9.350 When the information coming into the HCC's possession during the investigation is looked at sequentially it is clear that a situation was being uncovered in which patient safety could not be properly ensured. Not only were frightening and persistent lapses in standards becoming evident, their very existence called into question the competence and capability of the Trust's leadership and management.

9.351 Were the General Medical Council (GMC) or the Nursing and Midwifery Council (NMC) to be given evidence of similar lapses on the part of a healthcare professional, they would almost certainly exercise their interim powers of suspension or imposition of conditions of registration. They would do so not as a punitive measure, and not to predetermine the outcome of their investigations or disciplinary process, but to protect patients and the public. In the case of regulated organisations, the position is more complicated. It is often not practical to take steps to close a service, let alone a whole hospital, but it is unacceptable to find deficiencies of the nature described in Dr Wood's letters and, while leaving the public in ignorance of those findings, to continue relying on the assurances of the provider's management that they are taking action. Such assurances had been given before and were being found by the investigation to have remained unfulfilled. At the very least, some form of external performance management presence was required at the Trust to oversee interim arrangements for protecting the public.

9.352 The system at the time did not allow the HCC to take that sort of action and the culture did not encourage it to advise other organisations how to do their jobs. It is therefore not surprising that neither the investigation team nor the higher echelons of the organisation were thinking in those terms. If there is a criticism to be made it is that they did not spell out with sufficient clarity the safety implications of the findings in terms of the increased level of risk presented to patients.

Processing of the draft report

9.353 It is clearly desirable that important and complex reports of the nature produced by the HCC on the Trust are subjected to some process to confirm that the report is factually correct and to allow a reasonable opportunity for those criticised to respond. The HCC attempted this, but in retrospect the process was not entirely satisfactory. What was shared did not allow those it was intended to criticise an opportunity to consider the evidence those criticisms were based on. A balance has to be found in such an exercise between disclosing the whole report, which is undesirable because of the potential for damaging leaks, and disclosing no evidence, making it difficult for constructive comment to be offered.

Communication about the investigation to other agencies

9.354 In *Chapter 18: Medical training* and *Chapter 12: Professional regulation*, consideration has been given to communication around the initiation and progress of the HCC's investigation by PMETB, the Deanery and by the GMC in both its professional regulation and training capacities. The evidence showed some confusion about who was told what and when. Some reliance was placed by the HCC on its public announcement of the investigation and various exchanges which owed something to chance occasions. There does not appear, on the part of any of these agencies, to have been a methodical approach to offering or obtaining information about the investigation, its progress and its significance for their own roles. As a result, there

was a lack of timely consideration of these issues and a lack of shared understanding of the importance of the investigation for each organisation's regulatory responsibilities.

9.355 The risks consequent on this form of confusion have been reduced by the development of risk summits and a more coordinated approach to the sharing of information.

Effectiveness of the Healthcare Commission and the regulatory system

9.356 The system of regulation which the HCC was given to run failed to prevent or detect, over three-quarters of its lifetime, what has been described as the biggest scandal in NHS history. At the same time, it was the first organisation out of the plethora with relevant responsibilities to identify serious cause for concern and to take the action which led to the full exposure of the scandal. At the heart of the failure was the concept of the core standards and the means of assessing compliance, the AHC. The success was due to an eventual refusal to accept glib assurances about mortality rates and to a willingness to take the only action available to establish the true level of concern, namely a thorough and challenging investigation of the true facts on the ground.

9.357 The core standards suffered from a number of deficiencies. They lacked acceptance at the very place where acceptance was vital, namely front-line clinical staff. Although they were the subject of consultation, many of the objections raised were dismissed, and the standards were more or less imposed on a new regulator which expressed unease about them. Therefore, the standards were not embraced or well understood by those who were expected to put them into practice or to enforce them.

9.358 A further difficulty was that the standards included a confusing mixture of the general and the specific, core standards and aspirations. They were expected to do too much: to set a minimum below which no provider should fall, to include targets in areas of particular interest to Government and to be a basis for comparing providers and assisting the public in making choices.

9.359 The assessment process also suffered a number of defects. Principal among them was the reliance on self-assessment and declaration as the basis of regulation. Of necessity, only a small proportion of such assessments could be checked or audited directly by a national regulator. The system relied on the ability and honesty of the regulated organisations to undertake their assessments accurately while observing the spirit of the standards, as well as the letter. Of course if such virtues could genuinely and universally be relied upon there would have been no need for regulation at all. Safeguards are needed because experience shows that not all organisations are competently or honestly led and not all deliver a proper standard of service. The more centrally controlled a public service is, the more those safeguards can arguably be provided by a publicly accountable performance management system. The more autonomy the front-line providers are allowed from such a system, the greater the need for a regulator to detect non-compliance with standards and to take appropriate enforcement action.

9.360 The period under review in this Inquiry was one of transition from one end of the spectrum to the other, from central control to greater autonomy; a period in which the loosening of central reins went faster and more effectively than the development of the regulatory oversight required to accompany it. Having set up a new system of regulation under the HCC, which for all its faults was an advance on what went before, the demands of embedding and developing new concepts were compounded by a decision to abolish it wholesale before it had really got going. Inevitably, this slowed the development process while resources and attention were devoted to the running down of one organisation and the setting up of yet another.

9.361 While the importance of detailed communication and cooperation with other regulatory and oversight bodies was recognised in the legislation, and followed up by the concordat and memorandum of understanding, the resulting systems spectacularly failed to ensure that the most basic information was known where it was needed. Thus, the concerns raised by peer reviews remained unknown to the HCC, as did the Trust's application for FT status. Monitor was not informed of the HCC's increasing concerns and intentions to launch an investigation. Too many assumptions were made that others would be aware of important information.

9.362 The checks put in place by the HCC to verify self-declarations were inevitably a net with a wide mesh through which inaccurate self-assessment and deficiencies in practice could pass undetected. A large proportion of HCC resources were devoted to processing the declarations and publishing overall results, which were of limited use to the public. The laudable development of a coordinated database of indicators which might suggest areas of concern was in its infancy. However, well developed indicators flagging up potential concerns could be masked by other indicators interpreted as reassuring. In any event the focus was on examining providers' apparent performance in relation to standards, most of which focused on the presence of theoretical systems, not on real achievements and outcomes for patients.

9.363 The other side of the coin from communication is the coordination and dissemination of important information in a useable form.

9.364 The HCC recognised these issues and did not rest entirely on the AHC, but sought to develop other means of detecting deficiencies. Its regional offices were designed to place its presence close to the providers, to enable it to pick up local expressions of concern. This failed to detect problems at the Trusts in part because relevant information was not received and in part because, along with so many other parts of the healthcare system, there was insufficient sensitivity to the implications for patients of the information that was available.

9.365 In the end what succeeded in bringing the problems to light was the HCC's persistence in seeking to find a way of using mortality data, in the face, it has to be said, of considerable resistance. While some mild criticism might in theory be appropriate of the speed with which the HCC reacted to the alerts relating to the Trust, this method was in embryonic form at the time.

9.366 What was undoubtedly a success, for which those involved are entitled to considerable credit, was the achievement of the formal investigation to root out the full extent of the appalling problems at the Trust. If criticism can be made of some of the detail of how the investigation was carried out, there is no doubt that without what was done many more patients would have had to suffer before any effective action was taken. The investigation demonstrates how powerful the combination of direct observation of practice, contact with patients, families, front-line staff and examination of real cases can be, as opposed to a reliance on files of policies, committee minutes and overall figures. This is not to say that examination of systems is not important, but it is not and never will be sufficient.

Overall conclusion

9.367 The HCC faced an enormous challenge from its creation until its demise, a relatively short time later. It was a more ambitious and comprehensive attempt at regulation than had informed the structure of its predecessor, but inevitably it was hampered in the progress it could make given the announcement of its prospective abolition so soon after it began work. It was given new standards to regulate, and compliance with these proved difficult to assess a practice. The need to monitor compliance had to be balanced against the requirements of proportionality. The experience of the assessment of the Trust indicates that the standards and the process by which compliance was monitored and followed up were insufficiently sensitive and effective to bring its serious problems to light. However, the HCC's investigation of the Trust in 2008 was what finally exposed the Trust's deficiencies. The conduct of the investigation showed the value of intensive and thorough inquiry in such a case. The time taken over this was criticised by some, as was the absence of any recommendation for intervention before the publication of its final report. However, other agencies such as the WMSHA and Monitor were also aware of the highly critical interim findings and in practice were in a position to take such action as they saw fit to protect patients if they had felt this was necessary.

9.368 In Professor Kennedy's view the real lessons of the Mid Staffordshire experience were about the need to create a culture of care. He believed that a good regulatory system had a role to play in promoting such a culture:

... regulation can play a role in helping to create this culture, albeit a limited role. I believe, Mr Chairman, that patients deserve a system of external, independent accountability, which adopts the views of patients and those who care for them as to what good care is all about, and seeks to promote patients' interests along three axes that the care is safe, that it's of good quality, and the patients have as good an experience of that care as is possible.[330]

9.369 It is important to recognise that any system of regulation has its limitations. Like the police who are better at crime detection than crime prevention, regulators are likely to be more effective at retrospective inquiries to establish what has gone wrong than they will be at preventing deficiencies occurring in the first place. Regulators are always going to be more distant from the provision of services than the ward sister or the provider's Chief Executive.

9.370 As Professor Kennedy put it:

There are a million contacts between patients and those who care for them every 36 hours. To keep track of that ... by periodic three-yearly visits is self-deception. Indeed, if you were to use visits with the regulatory [structure] *that would require, you would have half the National Health Service looking at the other half and travelling the country to achieve that. In my view, the process of achieving a good system of accountability can only effectively be achieved by having regular data about agreed matters along these three axes accompanied by targeted and random visits, with the results being published. The goal must be that the data is generated virtually in real time, to allow for surveillance and prevention and to prevent repeated catastrophic failures. This can act as a spur to good performance and improvement, but the key will always lie, in my view, with professionals providing and managing the care of patients, and the culture that they create and they work in.*[331]

9.371 The key elements of effective regulation of healthcare must be:

- Standards that have their source in what is important for patients and are accepted by the healthcare staff who have to comply with them. It is therefore important that they are informed by the outcomes desired by patients, and by what healthcare professionals accept is possible in practice. They have to be 'owned' and understood by patients, the public and the professionals who have to apply them. Such standards must clearly identify the fundamental requirements of safety and quality that are acceptable and below which no service should be permitted to fall. Regulatory standards should not be concerned with aspirational improvement: that is a matter for the commissioners of service;

330 Kennedy T77.165
331 Kennedy T77.165–166

- Compliance with regulatory fundamental standards must be capable so far as possible of being assessed by measures which are understood and accepted by the patients, the public and healthcare professionals. The measures should include measures not only of clinical outcomes, but of the suitability and competence of staff and the culture of organisations;
- Non-compliance with the fundamental standards should not be tolerated;
- A coordinated collection of accurate information about the performance of organisations must be available to providers, commissioners, regulators and the public. Such information must be available in as near real time as possible and should be capable of use by regulators in assessing the risk of non-compliance. It must include not only statistics about outcomes, but must take advantage of all safety-related information, including that capable of being derived from incidents, complaints and investigations. It is not the source of the information that matters, but its implications for patient safety and the quality of care;
- A systems regulator's principal function should be to enforce compliance with fundamental standards by focusing its monitoring on organisations and services in respect of which there is reasonable cause to suspect that service below the fundamental standard has been delivered. This can only be achieved by a system which seeks out and uses information, but is not a slave to it, and which always has regard to the potential risks to patients disclosed by information about deficiencies, rather than waiting for proof of harm or non-compliance;
- Effective detection of non-compliance with standards for patients cannot be achieved solely by a remote examination of policies and systems, but almost invariably requires contact with patients and staff and observation of environments and practice.

Summary of recommendations

Recommendation 14

In addition to the fundamental standards of service, the regulations should include generic requirements for a governance system designed to ensure compliance with fundamental standards, and the provision and publication of accurate information about compliance with the fundamental and enhanced standards.

Recommendation 26

In policing compliance with standards, direct observation of practice, direct interaction with patients, carers and staff, and audit of records should take priority over monitoring and audit of policies and protocols. The regulatory system should retain the capacity to undertake in-depth investigations where these appear to be required.

Recommendation 27

The healthcare systems regulator should promote effective enforcement by: use of a low threshold of suspicion; no tolerance of non-compliance with fundamental standards; and allowing no place for favourable assumptions, unless there is evidence showing that suspicions are ill-founded or that deficiencies have been remedied. It requires a focus on identifying what is wrong, not on praising what is right.

Recommendation 30

The healthcare regulator must be free to require or recommend immediate protective steps where there is reasonable cause to suspect a breach of fundamental standards, even if it has yet to reach a concluded view or acquire all the evidence. The test should be whether it has reasonable grounds in the public interest to make the interim requirement or recommendation.

Recommendation 34

Where a provider is under regulatory investigation, there should be some form of external performance management involvement to oversee any necessary interim arrangements for protecting the public.

Recommendation 35

Sharing of intelligence between regulators needs to go further than sharing of existing concerns identified as risks. It should extend to all intelligence which when pieced together with that possessed by partner organisations may raise the level of concern. Work should be done on a template of the sort of information each organisation would find helpful.

Recommendation 36

A coordinated collection of accurate information about the performance of organisations must be available to providers, commissioners, regulators and the public, in as near real time as possible, and should be capable of use by regulators in assessing the risk of non-compliance. It must not only include statistics about outcomes, but must take advantage of all safety related information, including that capable of being derived from incidents, complaints and investigations.

Chapter 10
Regulation: Monitor

Key themes

- Monitor's approach to the quality of care during 2005–2009 was that it was not its direct concern but that it would suffer if a Foundation Trust's (FT's) finances and governance were not kept in good order.
- There was tension between Monitor and the Department of Health (DH) with regard to the extent and significance of its independent status.
- There was some lack of clarity between Monitor and the Healthcare Commission (HCC) as to their respective regulatory roles and, at least initially, infrequent contact between their leadership.
- The authorisation of the Trust was accompanied by the perceived need to send it an unpublished side letter setting out further requirements and expectations.
- Monitor became aware of the detail of the concerns leading to the commencement of the HCC investigation in May 2008. Its reaction was to express concern at the proposed length of the investigation and to expect the Trust to take necessary remedial action immediately.
- The HCC letter of 23 May 2008 setting out serious concerns about the A&E service caused a reduction of confidence in the Trust at Monitor, but this did not displace an assumption that it could wait for advice from the HCC on intervention.
- Throughout the HCC investigation Monitor was concerned at its length but continued to await its final outcome and any recommendations from the HCC before making a decision on intervention.
- Monitor developed further concerns about the governance of the Trust from a governance review report in November 2008 and set out expectations for the Trust Board, but continued to await the outcome of the investigation.
- In February 2009 Monitor's Chair informed Martin Yeates that Monitor thought that the Trust was probably in significant breach of its authorisation but had no current intention to require his removal from post. It remained its intention not to make a decision on breach until after receipt of the HCC report. The Trust Chair was warned she would probably be required to step down. At the same time Monitor was exploring possible candidates for the post of Trust Interim Chair and Chief Executive.

- After the publication of the HCC report Monitor found the Trust to be in significant breach.
- A review commissioned by Monitor of its own actions concluded that there was room for improvement in its performance.
- Steps could be taken to improve the calibre, competence and training of FT Board members and governors.
- In recent developments, Monitor has taken steps to assess the sustainability of clinical care, but there is a case for joining together some of its functions with those of the CQC.

Introduction

10.1 The involvement of Monitor in the role of assessing applications of trusts in general, and the Trust in particular, has been considered in *Chapter 4: The foundation trust authorisation process*. This chapter considers the role of Monitor in relation to the Trust and as a regulator more generally.

10.2 The Trust was only authorised as an FT very shortly before the HCC announced its investigation, but the period that followed has provided an illuminating stress test of the system for regulating FTs where they have been found to have failed systemically to provide the service to patients that should be expected.

10.3 Monitor's regulatory interaction with the Trust during this period had a number of characteristics that were unlikely to have been unique to its dealings with that organisation:

- Monitor energetically and constantly sought to affirm its independence.
- It largely waited for the HCC to conclude its investigation before formally considering whether to take regulatory action.
- Once the report was published, it acted swiftly to engineer the removal of the existing Trust leadership.
- Monitor reviewed self-critically its operations in the light of its experience with the Trust.
- Monitor remains largely reliant on the healthcare regulator for regulatory oversight of compliance with clinical standards and clinical governance systems, but retains an involvement in reviewing all forms of governance.

Legislative framework

10.4 The policy background to the FT concept has already been summarised in *Chapter 4: The foundation trust authorisation process*.

Structure

10.5 Monitor was established in 2004, under the Health and Social Care (Community Health and Standards) Act 2003, as the independent regulator of FTs. Its members, of whom there were to be no more than five, were to be appointed by the Secretary of State for Health. It was empowered to regulate its own procedures and required to report annually, directly to Parliament.[1]

Functions duties and powers

Functions

10.6 Monitor's functions included:

- Establishment and maintenance of a register of NHS FTs;
- Assessment of applications for FT status;
- The authorisation of NHS trusts as NHS FTs.[2]

Terms of authorisation

10.7 Monitor could grant authorisation on any terms it thought appropriate, including a power to enter and inspect the FT's premises. There were no powers to grant conditional authorisation. It was necessary to include in the authorisation a requirement that the FT disclose to it such information as may be specified by the Secretary of State for Health.[3]

Duties

10.8 Monitor's duties included:

- Making an annual report;[4]
- Cooperation with the HCC;
- Provision to the HCC of any information about healthcare it considered would assist the HCC in discharging its functions.[5]

Powers

10.9 Monitor was given power to require any health service body to give it information it required for the purpose of performing its functions.[6]

1 Health and Social Care (Community Health and Standards) Act 2003 section 2 and sch 2, para 11; www.legislation.gov.uk/ukpga/2003/43/contents ; now consolidated in the National Health Service Act 2006 section 31 and sch 8; www.legislation.gov.uk/ukpga/2006/41/contents
2 National Health Service Act 2006, sections 35 and 39; available at: www.legislation.gov.uk/ukpga/2006/41/contents
3 National Health Service Act 2006, sections 35(4), 48(1) and 49; www.legislation.gov.uk/ukpga/2006/41/contents
4 National Health Service Act 2006, schedule 8, paragraphs 11; www.legislation.gov.uk/ukpga/2006/41/contents
5 WS0000039629, para 18, Health and Social Care (Community Health and Standards) Act 2003, s61, www.legislation.gov.uk/ukpga/2003/43/contents; Moyes WS(2)
6 National Health Service Act 2006, section 48(2), www.legislation.gov.uk/ukpga/2006/41/contents

10.10 It had powers of intervention in an FT where it was satisfied that:

- The FT was not complying with any term of the authorisation or any other statutory requirement; or
- The FT had failed to comply with any such term or requirement and was likely to do so again; and, in either case
- The non-compliance or failure was "significant".

10.11 In such circumstances, Monitor could:

- Require the FT, its directors or governors to do or refrain from doing specified things within a specified period;
- Remove any or all of the directors or governors and appoint interim directors or governors.[7]

10.12 Monitor's powers in this regard continue under the regime to be put in place pursuant to the Health and Social Care Act 2012.

10.13 Since the events with which this Inquiry is principally concerned, subsequent legislation proposed through the Health Act 2009 to enable the deauthorisation of FTs. Monitor was to be given the power to notify the Secretary of State that an FT was contravening or failing to comply with, or had contravened or failed to comply with, a term of its authorisation, and that the seriousness of the contravention or failure was such that it would justify the Secretary of State to order deauthorisation. Conversely, if it appeared to the Secretary of State that there were grounds for Monitor to be satisfied that such steps should be taken, the Secretary of State was to be empowered to request that Monitor exercise its powers to do so.[8] These provisions were brought into force only to enable Monitor to consult on publishing guidance relating to what matters it proposed to consider when making a decision under these provisions.[9]

10.14 The Health Act 2009 contained a further power to initiate deauthorisation, which was also brought into force, that enabled Monitor to start the process where:

- It had served a notice on an FT, requiring it to do specified things or to refrain from doing such things, within a specified time;

7 National Health Service Act 2006, section 52, www.legislation.gov.uk/ukpga/2006/41/contents
8 Health Act 2009, section 15, www.legislation.gov.uk/ukpga/2009/21/contents amending the National Health Service Act 2006 by the insertion of sections 52A–52E
9 Health Act 2009 (Commencement No. 1) Order 2010/30, www.legislation.gov.uk/ukpga/2009/21/contents

- It was satisfied that further exercise of its powers of intervention would not be likely to secure the provision of the goods and services which the FT is required by its terms of authorisation to provide.[10]

10.15 Under the provisions of the Health and Social Care Act 2012, the powers of deauthorisation described above have been repealed. Under this Act there remains a power vested in Monitor to appoint a trust special administrator for an FT, but only where satisfied that it is or is likely to become unable to pay its debts. If such an order is made, the CQC must provide a report on the safety and quality of services provided by the FT.[11]

10.16 Professor Kieran Walshe, an expert in health policy who has assisted the Inquiry, commented that Monitor's powers of enforcement were "not very well graduated". In his view, in relation to the position at the time of the oral hearings, it had the opportunity to take informal action but, he argued, its next step was to intervene and remove the board.[12] This is not correct in a literal sense. As has been seen, the enforcement powers included a power to direct the FT to do any specified thing and the Act imposes no limitations on what that "thing" might be. As will be seen, what brought about limitations on practice was the policy, encouraged by the DH and accepted by Monitor, that it was not a "performance manager" and was not to "micro-manage" FTs: the focus was not to undermine the responsibility of FT boards.

Creation of Monitor

10.17 Dr William Moyes started work as Executive Chairman of Monitor in November 2003. He commissioned a report from McKinsey into Monitor's state of readiness to take up its duties when it came into formal existence in April 2004. This report led Dr Moyes to believe that little had been done to formulate a coherent picture as to how Monitor might operate as a regulator.[13] This was, perhaps, not surprising, as the Government's intention appears to have been to give those appointed considerable freedom in setting up Monitor, enabling it to regulate its own procedure and make any arrangements it considered appropriate for the discharge of its functions.[14] This did, however, mean that Dr Moyes and colleagues had to work under considerable time pressure to be ready to authorise applicants as from April 2004.

10.18 Dr Moyes observed that the temporary staff assigned to Monitor from the DH appeared to envisage a more interventionist role in the day-to-day management of FTs than he thought appropriate. It was also made clear to him by senior DH officials that Monitor was not expected to duplicate the role of the HCC.[15]

10 National Health Service Act 2006, sections 52–54, www.legislation.gov.uk/ukpga/2006/41/contents
11 National Health Service Act 2006 section 65D as substituted by the Health and Social Care Act 2012 section 174, with effect from November 2012
12 Walshe T8.85
13 Moyes WS(2) WS0000039624, para 7
14 National Health Service Act 2006, s47 and sch 8, para 6, www.legislation.gov.uk/ukpga/2006/41/contents
15 Moyes WS(2) WS0000039624–5, para 7

Approach to authorisation and regulation

10.19 As described in *Chapter 4: The foundation trust authorisation process*, Monitor interpreted the statutory conditions for authorisation as requiring it to adopt a risk management approach and to be "confident" and "able to provide assurance to Parliament" that the applicant was (or would be, if authorised):

- Legally constituted;
- Locally representative;
- Financially viable;
- Well governed.[16]

10.20 Dr Moyes thought the appropriate method of assessment was akin to the due diligence process that a company would go through if it were applying for a stock exchange listing. He wanted to be confident that FT Boards could run their organisations independently and competently while taking responsibility for doing so. He did not want to see Monitor acting as a corporate headquarters. In his view, this meant that a number of aspects needed to be considered carefully in the assessment process:

- He wanted to make sure that FTs were capable of keeping their finances in order:

 ... because I knew that if they did not, quality of care would suffer. In my experience, if an acute hospital loses even 2% of its income without having planned for this, its finances will be in serious difficulties, and it will often respond to that by removing staff throughout the organisation, rather than focusing on particular services which may not be clinically or financially sustainable.[17]

- He considered that finding board members with sufficient experience of running complex organisations was a problem for trusts. The same was true of governors. Therefore, he ensured that Monitor took a "tough line" on board members, particularly non-executive directors, although he did not think that imposition of a term requiring directors to have a specified qualification or accreditation would be appropriate:

16 CURE0007000040, Applying for NHS Foundation Trust status: Guide to Wave 3 applicants (November 2005), Monitor, para 2.4
17 Moyes WS(2) WS0000039626, para 11–12

Monitor became known for taking a tough line on the quality of boards, particularly non-executives, and a lot of people who were non-executives of applicants stepped down before the authorisation process started, and that became not at all uncommon. So on the one hand, Monitor was quite clear and made it quite clear that we expected to see boards that understood the business of the hospital and had the skills and experience or had some evidence of the skills and experience necessary to do the job. For example, having a qualified accountant to chair the audit committee, that seemed to us to be something that was … highly desirable to us for businesses of this scale. But if we had set an authorisation condition, we were then putting ourselves in a position, I think … that we would have to have in … some sense a continuing role in vetting the appointment of board members.[18]

10.21 He thought that there was little point in insisting on such a requirement when the non-executive directors could resign the day after authorisation and be replaced by people without the relevant qualifications, as the Act gave the power of appointment to the governors, rather than to Monitor. He was not against the introduction of a general "fit and proper person" test.[19]

10.22 He was and remains concerned about Monitor's position with regard to FT governors. While Monitor could ensure that there was a properly elected shadow board of governors in place before authorisation, it could only take action about them afterwards if the FT was in significant breach of its terms of authorisation.[20]

Approach to quality of care

10.23 The Act did not specify what, if any, role was to be played by Monitor in regulation of quality, but Dr Moyes felt that it would not be right for his organisation to assess or monitor quality, this being the domain of the HCC. He felt that "Parliament could not be supposed to have wanted both bodies to duplicate roles".[21] He pointed out that if Monitor were to have played a role in assessing quality of care, it would have required "experienced clinical staff", for which it had not been given the resources.[22]

10.24 However, it was appreciated that Monitor's powers of intervention could be used where a breach of the terms of authorisation related to clinical activities, and it was ensured that authorisations were drafted to enable this to happen.

18 Moyes T92.101–102; Moyes WS(2) WS0000039627, para 14
19 Moyes WS(2) WS0000039627, para 14
20 Moyes WS(2) WS0000039626–7, para 13
21 Moyes WS(2) WS0000039629, para 19
22 Moyes WS(2) WS0000039628–30, paras 17–20

10.25 Thus, the system as set up included the curious feature that the HCC, as the body charged with regulating the standards of clinical service, had to rely, where an FT was concerned, on another body, Monitor, to take regulatory action where there had been non-compliance:

> *... there was an independent body to inspect and report, and an independent body to intervene and put right.*[23]

10.26 Monitor's powers were not conditional, in this respect, on receiving a recommendation from the HCC, and it could act on its own initiative or on information received from another source such as a Royal College.

10.27 Monitor did not divorce itself entirely from consideration of quality of care. In 2005, at the request of the then Secretary of State of Health the Rt Hon John Reid MP, it carried out a review of the first wave of applications for FT status (see *Chapter 4: The foundation trust authorisation process*). However, the measures of quality look to appear largely to have been restricted to existing Government targets and some patient survey responses, with no outcomes relating to treatment or mortality.[24]

The autonomy of foundation trusts and the independence of Monitor from the Department of Health

10.28 The policy intent behind the creation of the FT concept was to distance the operational provision of healthcare from the DH and its Ministers and to devolve responsibility for the running of healthcare providers to their directors under the general local supervision of governors, with leverage operated on performance by the commissioning primary care trusts (PCTs). The extent of this was set out by the Rt Hon John Reid MP, then Secretary of State for Health, in a letter to the speaker on 25 March 2004, which was followed by a Written Ministerial Statement on 30 March 2004. He stated to the speaker of the House of Commons that, in future, he would not be willing to answer questions about the detailed operational management of FTs and would only answer questions about Monitor expressly on its behalf.[25] The Rt Hon Andy Burnham MP summarised the Government's policy as follows:

> *... power and responsibility was ... firmly placed at the local level with the Foundation Trust reform, where organisations were expected to account for themselves to their own local population.*

23 Moyes T92.105
24 WB/1 WS0000062961
25 MON0000000232, Letter from the DH to Mr Speaker Martin on Ministerial accountability for NHS foundation trusts (dated 25 March 2004)

10.29 He saw there to have been a real recognition that improvement of the health service could not be achieved by "diktats and edicts from London" but at a local level with local accountability.[26]

10.30 However, the Secretary of State retained overall responsibility for the provision of the health service. As a result, there was a recognition that it was not practical for the separation between Whitehall and local trusts to be complete. As Mr Burnham explained, there was an inherent conflict built into the system:

> *You're putting your finger on a very real tension that a Minister has to manage. At all times I and other ministerial colleagues respected the independence of these organisations to advise us. However, we also pointed out to them on many occasions that it would be – it would be me standing on the floor ... of the House of Commons answering a question from a constituency MP and having to give an assurance to that person that their hospital was safe ... ultimately, Ministers are responsible for upholding public confidence in individual hospitals and indeed in the National Health Service more generally. So it follows, therefore, that there has to be a real basis of understanding between regulator, department and Minister about what statements are being made* [and] *on what basis they're being made ...*[27]

10.31 A Memorandum of Understanding between Monitor and the DH, signed in summer 2004, sought to set out the parameters of their relationship.[28] This document recognised the DH's responsibility for securing the availability of comprehensive healthcare and for assuring performance of the service. In relation to FTs and Monitor, the DH's responsibilities were said to be:

- Ensuring the policy and operational frameworks for the NHS were consistent with FTs operating effectively under the terms of their authorisation;
- Allocating resources to ensure commissioners could purchase appropriate healthcare provision; and
- Ensuring that Monitor had appropriate resources.

10.32 Monitor's responsibilities were:

- assessing, authorising and regulating FTs within the statutory framework:

 ... in a manner consistent with the performance by the Secretary of State of his duties ...;

- cooperating with the HCC as required by the Act and other "appropriate" NHS bodies;
- reporting to Parliament as required by the Act.

26 Burnham T115.9–10
27 Burnham T115.23–24
28 Masters WS0000035324, para 34; AM/6 WS0000035724

10.33 It was agreed that there needed to be a close relationship between Monitor and the DH and its Ministers:

> *... to ensure that the Department and* [Monitor] *can effectively perform their statutory functions to ensure that the NHS continues to deliver a high and improving quality of service to the public.*

10.34 This required, among other things, regular contact, good communication and a willingness to support each other in the discharge of their duties.

10.35 Two overarching principles were set out:

> *The Department fully acknowledges the independence of* [Monitor] *and that NHS Foundation Trusts are not subject to direction by the Secretary of State;*
>
> [Monitor] *acknowledges that the statutory responsibilities of the Department and Ministers require them to continue to take an interest in how* [Monitor] *and* [FTs] *are contributing towards satisfactory discharge of those statutory responsibilities ...*

10.36 Adrian Masters, Director of Strategy at Monitor, formed the impression that, in practice, there was sometimes a tension between the DH and Monitor with regard to its policy on the status of FTs.[29]

10.37 He gave as an example of this tension an episode in 2007–2008, in the aftermath of the HCC's report on the *C. Difficile* outbreak at Maidstone and Tunbridge Wells NHS Trust. On 15 October 2007, Sir David Nicholson, NHS Chief Executive, emailed all chief executives of NHS and foundation trusts drawing attention to the report:

> *I want to ensure that everyone with leadership responsibility within every NHS organisation actively considers the Healthcare Commission report ... and what further action they need to take ... I am clear that the failures highlights* [sic] *in the report must not be repeated ...*
>
> *Where senior management and trust boards fail to act to deliver good quality infection control they must and will be held accountable ... I expect you to ensure that good practice in infection control is day to day core business. This is what patients expect and the NHS has a duty to deliver.*

29 Masters WS0000035324, para 35

... I would urge each of you to ensure that the recommendations laid out in this report are fully understood by your board and that any local actions necessary are implemented with immediate effect.[30]

10.38 On 19 October 2007, Dr Moyes wrote to Sir David. While expressing agreement with his anger at what had happened in that NHS trust, he expressed "discomfort" at:

... the fact you have written direct to the Chief Executives of foundation trusts expressing expectations in terms which will be interpreted as instructions ...

I am concerned that your letter may have sown in some minds the seeds of doubt about the precise nature of accountability for foundation trusts and have been interpreted as a signal that the independence of foundation trusts, which is a key to their success, is in danger of being eroded. I am sure that was not the intention ...[31]

10.39 He suggested that, in future, it might be appropriate for Sir David to write to providers jointly with Monitor and the HCC in similar circumstances.

10.40 Sir David replied in tones of some puzzlement on 12 December 2007:

I must admit that I do not fully grasp your point about instructions to NHS Foundation Trusts. As NHS Chief Executive I have an explicit responsibility to ensure that all NHS organisations have a clear and consistent view on how we expect them to respond to the challenges that the Healthcare Commission's report presents us with. That applies to NHS Foundation Trusts as much as to any other NHS organisation.[32]

10.41 He denied that his communication had challenged FT autonomy.

10.42 Dr Moyes sent a riposte on 31 January 2008.[33] He suggested that the NHS Chief Executive should direct such expectations to PCTs, as they commissioned care and, it appeared, were doing so with hospitals which were "dirty, badly managed or deficient in some other serious way". If an FT were to be found to be acting this way, the right approach was for the NHS Chief Executive to approach Monitor to invite it to use its statutory powers. He feared that otherwise, Monitor's ability to require compliance could be badly compromised.

30 MON0000000196, Emails between DH and Monitor regarding the Monitor response to the HCC report on *C. difficile* at Maidstone and Tunbridge Wells NHS Trust
31 WM/3 WS0000039810–1
32 WM/3 WS0000039812
33 WM/3 WS0000039813

10.43 Dr Moyes confirmed that he tried to ensure that the statutory framework was respected:

> *... in the face of regular (but not necessarily frequent) attempts by the Department and individual SHAs to direct Foundation Trusts to do, or no* [sic] *do, specific things, or to interfere in their internal management.*[34]

10.44 In general, he found that Monitor's relationship with the DH was "never ... a particularly easy one", and his impression was that many people in the DH were "hostile" to the concept of FTs, and were, therefore, sceptical about Monitor.[35]

10.45 The correspondence described above indicates a degree of over-zealousness on the part of Dr Moyes in protecting Monitor's independence. The outbreak of infection at Maidstone and Tunbridge Wells had appalling consequences for patients, and it is entirely understandable that the NHS Chief Executive would want to ensure that swift action was taken throughout the country to protect patients from a similar experience. By use of the language of expectation, he was avoiding issuing an instruction, while making it clear that accountability remained with the leadership of NHS trusts and FTs. To become preoccupied at such a time with the minutiae of language and the route of communication was inappropriate.

Monitor's relationship with other bodies

The Healthcare Commission

10.46 As described in *Chapter 2: The Trust*, Monitor refused to sign up to the concordat entered into by a number of other organisations. According to Anna Walker, former Chief Executive of the HCC, the reason given was that it would be of no use to Monitor, as it did not undertake inspections.[36] She was critical of this decision by Monitor:

> *I think that it would have signalled something important about working in partnership with all of us as a group, and I think that it would have strengthened the ties that we were then seeking to put in place anyway between the teams of staff to exchange information.*[37]

34 Moyes WS(3) WS0000074032, para 10
35 Moyes WS(2) WS0000039635, para 36
36 Anna Walker WS0000028576, para 110
37 Anna Walker T83.127

10.47 To this criticism, Dr Moyes responded that:

> *... Monitor never thought the Concordat was a bad initiative, it was simply not of assistance to Monitor in discharging its statutory obligations. The problem at which the Condordat was directed was that trusts were subject to multiple reporting and inspection regimes which could detract from their day to day affairs. In relation to foundation trusts, Monitor addressed this problem by rationalising the amount of information which each foundation trust needed to provide to the DH. The Concordat would not have added to this. In addition, Monitor's understanding of the operation of the Concordat would have been to channel all requests for information or visits through the HCC. Monitor was concerned that this would hinder its ability to run its own compliance system, and obtain information where it felt that it was needed, and could impede interventions in failing foundation trusts.*[38]

10.48 Adrian Masters responded that:

> *The Concordat was developed by inspecting bodies to remove unnecessary burdens associated with inspections, audits and reviews. This had no practical relevance for Monitor, because it did not operate a programme of inspections or audits, and it did not therefore sign the Concordat ... the Concordat is concerned exclusively with inspection, which is not one of Monitor's roles.*[39]

10.49 Dr Moyes acknowledged that, in the early days of Monitor, discussions with the HCC were infrequent and that this was a mistake. He also considered that Professor Sir Ian Kennedy, Chair of the HCC, and he did not succeed in building a good relationship.[40]

10.50 However, in September 2006 the two organisations signed a Memorandum of Understanding, the terms of which are described in *Chapter 9: Regulation: the Healthcare Commission*. In the same year, Dr Moyes's informal meetings with Anna Walker increased.[41]

10.51 In its closing submissions, Monitor accepts that the respective roles of Monitor and the HCC in quality governance were "not as clear as it might have been".[42]

Strategic health authorities

10.52 Monitor highlighted the importance it placed on establishing relationships with strategic health authorities (SHAs) at an operational level to understand wider regional issues, meeting with each quarterly to discuss the strategy in the region, commissioning intentions and regional

38 Moyes WS(2) WS0000039705–6, para 218
39 Masters WS0000035321, para 26
40 Moyes WS(2) WS0000039630, para 22–23
41 Moyes WS(2) WS0000039631, para 24
42 CLO000001051, *Monitor's closing submissions*, Part 2 – Narrative: Historical, para 87

financial issues which may have impacted on the performance of FTs in their area. Over time, the number of executive directors that attended was increased to ensure maximum benefit from the meetings.[43]

Primary care trusts

10.53 Monitor described its relationship with PCTs as "not always easy".[44] It appeared to Monitor that PCTs assumed that Monitor would support the FT in any disputes, an assertion that Dr Moyes denied. He told the Inquiry that Monitor thought that FTs and PCTs were bound to cooperate with each other and to comply with the terms of any contractual agreement. He felt that an FT's terms of authorisation were "an important lever" to help PCTs to secure the services it was entitled to expect.[45]

10.54 Dr Moyes stated that Monitor sought to encourage a partnership in which the PCTs would approach Monitor if they encountered any difficulties with FTs. Indeed, Monitor published (and still publishes) guidance to PCTs, for example on Monitor's role and powers.[46]

Patient groups

10.55 Monitor did not receive a large volume of correspondence from patient groups, nor did it solicit it. Such groups had other channels through which they could express their concerns, in particular through the HCC and the Parliamentary and Health Service Ombudsman (PHSO). Monitor did, however, receive summaries of complaints from the HCC in relation to FTs, which were valuable in observing any worrying trends or spikes in complaints about particular FTs.[47]

The Trust's terms of authorisation

10.56 Monitor's Board decided to authorise the Trust as an FT on 30 January 2008 and its authorisation was signed by Dr Moyes on 1 February 2008.[48]

10.57 The conditions of authorisation required the Trust to comply with:

- Any statutory requirements: these would have included the statutory requirements of compliance with HCC standards;
- Its conditions of authorisation;
- The terms of its constitution;
- Monitor's guidance, unless Monitor had agreed otherwise.[49]

43 CLO0000001052–3, *Monitor's closing submissions*, Part 2 – Narrative: Historical, para 91
44 CLO0000001053, *Monitor's closing submissions*, Part 2 – Narrative: Historical, para 92
45 Moyes WS0000039636–7, para 39; CLO0000001053, *Monitor's closing submissions*, Part 2 – Narrative: Historical, para 92–93
46 Moyes WS0000039636–7, para 39–40; CLO0000001053, *Monitor's closing submissions*, Part 2 – Narrative: Historical, para 92–93
47 Moyes WS0000039637–8, para 41; CLO0000001053–4, *Monitor's closing submissions*, Part 2 – Narrative: Historical, para 94
48 MON00030012128–37, *Terms of authorisation of Mid Staffordshire NHS Foundation Trust (1 February 2008)*, Monitor
49 MON00030012132, Authorisation of Mid Staffordshire NHS Foundation Trust, 1 February 2008

10.58 As noted from the review of the statutory powers of Monitor above, any significant failure to comply could entitle Monitor to exercise its enforcement powers, a point repeated in the conditions.

10.59 The Trust was required to comply with the principles of best practice of corporate governance, with Monitor's code of practice and guidance.

10.60 With express reference to quality, the authorisation required compliance with the core standards and any others issued by the Secretary of State.[50]

10.61 There was an obligation to disclose to Monitor any information that it might require.[51]

10.62 On 6 February 2008, Monitor sent a side letter to the Trust, picking up matters which had emerged during scrutiny of the Trust's application and, in particular, outlining Monitor's concerns about its ability to meet the longer term financial challenges, and the thrombolysis and A&E targets.[52] This letter was not published, unlike the terms of authorisation. Dr Moyes said that side letters were not published but that there was no reason why they could not be.[53]

10.63 A 2009 variation to the authorisation required compliance with the NHS Constitution, and the healthcare targets and indicators in the Compliance Framework.[54] Taken as a whole, the terms of the authorisation suggest that it was sufficient to require compliance with any quality standard issued by the Secretary of State, and regulated by the HCC or its successor, the CQC.

10.64 It was an undesirable practice for side letters to be issued without being made public. It is clear from the tone of the Monitor Board's deliberations at its meeting on 30 January that it had reservations about important matters relating to the governance of the Trust. Although, in its judgement, these matters did not preclude authorisation, they were matters to which attention should be paid. The public had a right to know that the Trust was, in effect, subject to continuing concerns. It was not then, and is not now, possible for an authorisation to be given on the condition that specified requirements are met, and such a qualification would not, in any event, have been practicable in relation to a matter such as achievement of long-term financial planning. However, publication of this letter might have made it more difficult for the Trust to trumpet its authorisation as arrival in the "premier league".

50 MON00030012133, Authorisation of Mid Staffordshire NHS Foundation Trust, 1 February 2008
51 MON00030012136, Authorisation of Mid Staffordshire NHS Foundation Trust, 1 February 2008
52 EL/21 WS0000036753
53 Moyes T92.44
54 MON00030012139, Authorisation of Mid Staffordshire NHS Foundation Trust, addendum 2

10.65 In fact, Monitor has, since October 2011, begun to publish side letters. The fact that it uses side letters has been made apparent since at least 2008[55] and can be seen in Monitor Board minutes as far back as March 2004.[56]

Monitoring of the Trust as a foundation trust

Reaction to the commencement of the Healthcare Commission investigation

10.66 Monitor knew, from shortly before the public announcement, that the HCC investigation was to take place and that it was likely to last 12 months.[57]

10.67 Before that, Monitor was also aware that the Trust was not free of problems:

- By reason of the matters mentioned in the side letter, it appreciated that it was not "perfect".[58] It had an amber risk rating as a result.
- On 5 February 2008, it received from the HCC by email information about the seven mortality alerts generated for the Trust.[59]
- On 28 February 2008, the HCC informed Ms Stephanie Coffey, Monitor's Relationship Manager for the Trust, that it had received information raising concerns about nursing care, and that it had conducted an unannounced inspection that week. It requested that Monitor pass on any information it had.[60]
- On 29 February 2008, Mr Martin Yeates, the Trust's Chief Executive, called Monitor to tell them about the unannounced visit and appeared to be shocked about this.[61]
- The following week, Martin Yeates telephoned again: he again expressed shock, this time at what he perceived to be the lack of objectivity of the HCC, as it appeared to him to have already made up its mind "about the severity of the issue before looking at all the evidence".[62]
- On 13 March 2008, it appears that Dr Heather Wood of the HCC spoke to Monitor to advise it of the decision to launch an investigation. Another telephone call was received from Martin Yeates, who told Ms Coffey that the concern was over mortality. This "disappointed" the Trust as it thought it had answered all of the HCC's concerns in this regard. He expressed the hope that the HCC would reconsider after meeting the Birmingham University team, which had reviewed the data.[63]

55 *Applying for NHS Foundation Trust Status: Guide to applicants*, (November 2008) Monitor, page 59, www.monitor-nhsft.gov.uk/sites/default/files/publications/Guide_for_applicants_Nov2008.pdf
56 www.monitor-nhsft.gov.uk/sites/all/modules/fckeditor/plugins/ktbrowser/_openTKFile.php?id=1488
57 Moyes WS(2) WS0000039654, para 73
58 M Carter T88.23
59 SC/3 WS0000035929
60 SC/6 WS0000035942
61 Coffey WS0000035899, para 35
62 SC/8 WS0000035947
63 SC/9 WS0000035949

- On 17 March, Heather Wood gave Monitor details of the form the investigation would take and informed Monitor that it would take about a year to complete.[64]

10.68 Dr Moyes's reaction at the time was expressed in an email on 18 March. While he was content that Monitor should cooperate with the HCC, he wondered whether there was a chance of the HCC undertaking a quick preliminary investigation to establish if there was a *prima facie* case for a more detailed investigation:

> *Although the process has to be thorough, this involves a big commitment of resources, and a big cost, in circumstances where there may be nothing very significant that isn't already known and being put right.*[65]

10.69 Nonetheless, he saw the importance of the Trust not waiting for a conclusion before acting:

> *I suggest that when you next speak to the CEO you make the point to him that we don't expect the trust to wait for the HCC to find things before they act. WE* [sic] *expect the FT to be proactive and look for failings that might concern the HCC and put them right. The danger is that they wait a year for the report and meanwhile improvements that might benefit patients are stalled.*

10.70 He told the Inquiry:

> *... from the very start I felt that 12 months was a very long time for the Healthcare Commission to spend on this investigation. Not because I thought it wasn't serious, but because it just seemed to me to be a very considerable use of resources that could have been directed at putting things right.*[66]

10.71 Dr Moyes accepted that if at that stage Monitor considered there had been a significant breach of the terms of authorisation so recently granted, it could have used its powers of intervention. A possible breach justifying action would have been a failure on the part of the Trust Board to be honest, open and cooperative, but he did not believe that evidence of that existed at that point.[67]

10.72 On 10 April, Stephanie Coffey went to the Trust to meet Martin Yeates, the Director of Nursing (Dr Helen Moss), the Head of Governance and the Head of Corporate Development. Before the meeting, the Trust's Compliance Manager showed Ms Coffey Cure the NHS's (CURE's) website. Ms Coffey was shocked by the stories she read there and was worried that some of them

64 WM/12 WS(2)0000039993
65 WM/12 WS(2)0000039993–4
66 Moyes T93.40
67 Moyes T93.40–41

referred to relatively recent events. She wondered whether the accounts were accurate and, if so, whether such things were still occurring.[68] At the meeting, the Trust representatives acknowledged that the action group's complaints were justified but asserted that the group had proved difficult to engage with.[69] It was stated that:

> *staff morale was lowering as they think it is unfair to be picked on although they are delivering improvements.*[70]

10.73 A number of other points were made at the meeting. These were covered by Ms Coffey in a briefing note for Dr Moyes for his meeting with the Trust on 8 May, and are referred to below.

- On 14 April, Dr Moyes and other Monitor officials met Mrs Toni Brisby, the Chair of the Trust. Dr Moyes reiterated the importance of the Trust rectifying issues as soon as possible. Mrs Brisby is recorded as having:

 ... noted that there was probably substance in some of the complaints about the care on the wards and the trust was looking to rectify these issues.[71]

10.74 At this stage, Dr Moyes told the Inquiry, he was, he thought, prepared to give Mrs Brisby "the benefit of the doubt".[72]

- On 24 April, Dr Moyes met Peter Shanahan, the Director of Finance and Capacity at the West Midlands SHA (WMSHA). Mr Shanahan expressed the WMSHA's support for the Trust in relation to the HCC review, which he described as "vindictive" and looking for evidence to support a pre-determined outcome. They understood that the Trust was taking "all necessary steps" to remedy shortcomings in the quality of care that might be identified in the report in advance of publication.[73]

10.75 Dr Moyes told this Inquiry that, in his view, the Trust had to work with the HCC, even if it did not like the HCC's approach.[74]

- On 8 May, there was a meeting between Monitor and the Trust. Those attending included Dr Moyes, Mrs Toni Brisby, the Vice Chair (Gerry Hindley) and Executive Directors of the Trust, including the Chief Executive, Martin Yeates. Monitor's briefing note for the meeting included a brief reference to Miss Julie Bailey, her experience of poor care in the wards, and feedback to the HCC from CURE members on the standard of care. It was noted that,

68 Coffey WS0000035901
69 SC/11 WS0000035956
70 SC/11 WS0000035958
71 Moyes WS(2) WS0000039654–5 para 75; WM/13 WS0000039996
72 Moyes T93.47
73 Moyes WS(2) WS0000039655, para 77; WM15 WS000004000
74 Moyes WS0000039655, para 77

at the time of the assessment of the Trust's application, neither the WMSHA nor the PCT had raised concerns about the quality of care. It went on:[75]

Discussions with the Trust show that there are issues with standards of care at the Trust but that the Executive team believe they have taken actions to improve, although the improvements will only be visible during 2008/09.[76]

10.76 The note described the triggers for the HCC investigation as being high mortality in specific specialties, areas highlighted by the Dr Foster Unit for which the Trust had not provided satisfactory explanations, and patients' complaints about the standard of care.

10.77 The feedback from the investigation to date included:

- A report that 60 members of the public were expected to be seen for interview as compared to 26 during the Maidstone and Tunbridge Wells investigation;
- The people interviewed had appeared credible:

 A consistent message has emerged from these interviews around the quality of care on general medical wards and care via the emergency pathway through to A&E and the assessment unit;

- All the people interviewed in the first two days were not connected with CURE;
- CURE had raised issues about staff under pressure, a culture of neglect, lack of communication, lack of control, non-implementation of action plans, and an ineffective complaints procedure. A list of 66 points commonly found in the CURE members' letters was attached;
- The Trust had seven complaints upheld by the HCC in the second and third quarters of 2005/06;
- It had had poor staff surveys in 2005/06 and 2006/07;
- It had breached the MRSA and cancer waiting time targets and was currently marginal for the A&E target;
- It was expected that the final report would be negative, but the Trust was arguing that this was due to the period under review:

 The Trust acknowledges that at least some of the complaints made by the local action group are justified. However they argue that:

 - *The Trust had serious financial and governance issues up until 2007/08 and improvements will only be seen from 2008/09 and beyond;*
 - *The Trust has tried on occasions to discuss with the local action group the issues they raised to explain the action taken, but the group has refused to meet them;*

75 WM/16 WS0000040002–14
76 WM/16 WS0000040005

- *The Trust has received positive feedback from some of the families of patients who died at the hospital.*

- The Trust had described its actions to date.[77]

10.78 The concerns listed in the briefing document included:

- The time taken to deliver improvements appeared to have been delayed, and there was little sense of urgency;
- Feedback from patients and the HCC continued to indicate significant shortfalls in the quality of care and complaints management;
- The extent to which historic financial challenges had impacted on the standard of care needed to be established;
- There was a question whether the Board had the requisite skills and strengths to recover financially, in terms of quality of care and its reputation.

10.79 At this point, Monitor was aware in some detail of the nature of the concerns which had prompted the investigation, namely mortality and a large volume of patient complaints about the quality of care. Even if, at the outset of the investigation, it was believed that the issue was one of mortality figures, it was now clear this was not the only point of interest for the HCC.

10.80 Monitor was now aware of matters which, on its own admission, would have prevented it authorising the Trust had it known about them in advance.[78]

10.81 The interaction with the Trust, as described in Monitor's contemporaneous notes, suggests that the Trust leadership was prone to contradictory characterisations of the position, was making non-specific statements about remedial action and that there was no assurance that acknowledged issues would be remedied rapidly. While the Trust leadership acknowledged that the complaints made by CURE and others were justified, it veered between asserting that they were old problems and warning that the solution would not be obtained for a while. It was also apparent that the confident assurances given in the latter stages of the assessment process were at the very least misplaced. It called into question the whole basis on which the application for FT status had been granted.

10.82 However, the response of Monitor to these developments was very muted. The immediate reaction at the time of the announcement of the investigation was to be concerned at the potential length of time of the investigation and the need to ensure that the Trust did not wait until the end of the process before starting to put things right. In contrast to its expectation of

77 WM/16 WS0000040007–9
78 Miranda Carter WS0000030602, para 66; T88.149; Hay WS0000041208, para 42

immediate action from the Trust, it took the view that it would be inappropriate to exercise its own statutory powers until the outcome of the investigation was known.

10.83 For Stephanie Coffey, the "key episode" was her meeting with the Trust on 10 April. However, she did not consider that what she learnt triggered a need to escalate the level of Monitor's concern in relation to compliance enforcement mechanisms, but only a need for "further thought". It did provoke a question in her mind around how the Trust had succeeded in obtaining authorisation.[79]

10.84 Following this meeting, Monitor asked the Trust to attend a monthly meeting to provide an update.[80] Dr Moyes was principally concerned that the Trust did not await the result of the investigation before taking remedial action, but he does not appear to have been immediately concerned about the overall performance of the Trust.

Healthcare Commission letter of 23 May 2008

10.85 The HCC's letter of 23 May 2008, the findings of which are described in detail in *Chapter 1: Warning signs*, included serious concerns about the management of A&E at the Trust. The letter suggested that there were risks to patient safety requiring immediate attention.[81] One conclusion was that there was an almost complete lack of effective governance.

10.86 Ms Coffey described this letter as a "key change":

> *This was the first time we had evidence that on a particular day in the near past, the services provided by the trust were unsafe.*[82]

10.87 The reaction of Edward Lavelle (then Regulatory Operations Director at Monitor) to the letter was:

> *... clearly when we received this letter it was an appalling set of circumstances that the Healthcare Commission had reported on. So there ... were obviously, in this area, a very substantial number of matters that had not been resolved.*[83]

10.88 These issues would have caused serious concern that the Trust had not been giving Monitor accurate information, but, in order for Monitor to intervene, these matters had to be proved by evidence, which the HCC had not yet provided.[84]

79 Coffey WS0000035901–2, paras 41–43
80 Coffey WS0000035897, para 24
81 HW/6 WS0000025130
82 Coffey WS0000035904, para 50
83 Lavelle T91.89
84 Lavelle T91.90

10.89 Dr Moyes became persuaded that it was "more than likely that there was a real problem at the Trust"[85] on receipt of this letter, which he described as a "tipping point"[86] at which his confidence in the Trust began to diminish rapidly. He did not "for a second" believe that the letter was overstating the case.[87] Dr Moyes was clear that the HCC had identified serious and alarming issues:

> *I was quite clear that the Healthcare Commission, although this might not have been the trigger for their investigation, were certainly going to be identifying – had identified serious failings in care, and certainly serious enough for, I think, anyone reading that letter to be very alarmed by it.*[88]

10.90 He told the Inquiry that, at this stage, assuming, which he was sure they did, the HCC had the evidence to support the assertions in the letter, there were grounds for intervention.[89]

10.91 He began to consider whether, at some stage, Monitor was going to have to exercise its statutory powers. He discussed this issue with colleagues, and whether Mrs Brisby and Mr Yeates could remain at the Trust, but he did not raise the matter for discussion at Monitor's Board. However, he could not recall what Monitor's view was of the statement in the HCC's letter about poor governance in relation to the A&E department. He noted that the HCC letter contained no recommendation to Monitor. He considered that the letter did not, as such, provide a sound basis for Monitor to intervene, because it consisted of provisional findings rather than a final report, and the HCC was less than half way through its investigation.[90]

10.92 He discussed the matter with Anna Walker, Chief Executive of the HCC, on 23 May 2008. A Monitor note suggests that she stated in this conversation that the HCC would agree to leave the Trust to undertake the required improvements in A&E without further action.[91]

Ipos-Mori Survey, May 2008

10.93 In May 2008, an Ipsos-Mori survey of patients, carers and visitors commissioned by the Trust was published.[92] Monitor, in its closing submissions, suggested that this survey was sufficiently positive to have been relied on in any legal challenge against the exercise of powers of intervention at that stage.[93] However, Dr Moyes's evidence was that he had not seen the survey before preparing his evidence. Had he done so, he would have told the Trust that it could pass the findings on to the HCC, but he would not have wanted it to "clutch at straws"

85 Moyes WS(2) WS0000039656, para 80
86 Moyes T93.69
87 Moyes T93.75
88 Moyes T93.69
89 Moyes T93.82
90 Moyes WS(2) WS0000039657, para 84
91 WM/19 WS0000040023
92 WM/20 WS0000040025–42; Moyes WS(2) WS0000039658, para 85;
93 CLO000001103, *Monitor's closing submissions*, Part 4 – Narrative para 203, footnote 520

and rely too heavily on the report, when it needed to focus on addressing the HCC's concerns.[94]

10.94 Superficially, the survey contained positive results: 88% of those who responded thought that, overall, the Trust was very or fairly clean, and 97% said overall that patients were treated with respect and dignity. However, other figures were less than encouraging:

- 7% of respondents from the Trust thought the quality of care at the hospital was fairly poor, very poor, or terrible.
- While 74% of respondents said the patient had been treated on every occasion with respect and dignity:
 - 4% said that respect and dignity had been shown, except on one occasion;
 - 15% were only prepared to say that respect and dignity had been shown most of the time;
 - 4% said it was only shown some of the time;
 - 1% said it had rarely been shown.[95]

10.95 In other words, 24% of respondents appear to have had one or more experiences of treatment lacking respect and dignity.

10.96 A legal challenge against intervention, based on the findings of the letter of 23 May, would most probably have required a stronger basis than this equivocal survey.

Meeting with the Healthcare Commission on 3 June 2008

10.97 On 3 June 2008, Monitor officials met Nigel Ellis (Head of Investigations at the HCC) and Dr Heather Wood to review the investigation. The HCC informed Monitor that if it was happy with the Trust's response to the 23 May letter, the HCC would continue the investigation and then look for assurance that action plans were being implemented effectively. If not satisfied, it would most likely look to the WMSHA or the DH to identify who should be put in place to rectify the issue. Edward Lavelle objected that, as the Trust was an FT:

> *... the SHA would have no role in performance management or making sure that the HCC recommendations were implemented.*[96]

10.98 He pointed out that Monitor had the power to address leadership issues, if necessary, but would need to base itself on the HCC recommendations that were supportable by evidence. Nigel Ellis is recorded as agreeing that this was a reasonable position.

94 Moyes WS0000039658, para 85
95 WM/20 WS0000040038
96 WM/21 WS0000040043–5

10.99 Dr Heather Wood expressed concern at a trend, noticed in interviews, about medication being withdrawn from patients on admission and not reinstated when necessary.

Dr Moyes's concerns at progress of the investigation

25 June 2008

10.100 A record made by Edward Lavelle of a meeting between Dr Moyes and Anna Walker, on 25 June, shows that he was dissatisfied with the progress of the investigation, as it was already clear to him that action was required:

> *... real concern is that if the HCC just keep bashing on with their reviews (5) the good bits of the hospital will decline as there is a fire fighting focus on the bad/findings – enough evidence already that material action is required and there is a need for an operational and strategic review (including viability of services provided – this would include discussions with SHA) ...*[97]

10.101 Mr Lavelle explained that he considered there was a different level of evidence needed to require the Trust to take action from that needed to justify an intervention by Monitor, and it was to the former that he was referring in this note in the phrase "material action".[98]

10.102 Dr Moyes told the Inquiry that his view at the time was that the HCC investigation took a "criminal prosecution style of approach" of investigating all possible offences and establishing the strength of evidence for a range of charges, rather than deciding that they had enough evidence for regulatory intervention. He considered this to be counter-productive:

> *The HCC could have presented a convincing picture of a hospital which needed reform without identifying issues in each ward. My view at the time was that there was a reasonable prospect that Monitor would end up using its statutory powers of intervention. The purpose of Monitor doing so would have been (as it eventually was) to secure an improvement to the quality of care provided to patients of the Trust as quickly as possible.*

10.103 He felt frustrated at not being able to use Monitor's statutory powers when the HCC was stressing that its investigation was incomplete and not in a position to make recommendations.[99]

7 July 2008

10.104 The HCC letter to the Trust of 7 July 2008,[100] which was copied to Monitor amongst others, expressed serious concerns arising out of patient complaints received by the HCC, as described

97 WM/22 WS0000040047
98 Lavelle T91.104–5
99 Moyes WS(2) WS0000039659, para 88
100 HW/7 WS0000025134–6

in *Chapter 9: Regulation: the Healthcare Commission*. Ms Yvonne Mowlds, a Portfolio Director at Monitor, reported this to Dr Moyes and summarised the key points as relating to concern over basic nursing care, medication, failure of clinical care and communications with relatives. She understood from a conversation with Dr Wood that the latter felt that many of the issues were being dealt with by the Trust.[101]

10.105 Dr Moyes expressed his frustration in a reply on 8 July 2008:

> *I'd like to persuade the HCC that enough evidence exists and that the focus should no longer be on establishing a watertight case – if we wanted to there is, I suspect, enough to allow us to intervene – but on getting change … What we don't know is whether the existing board, management team and clinical leadership can or cannot deliver permanent change on the scale required … On current plans it will be 9 months or so before the HCC will have completed its report. I'd like to persuade the HCC to shorten that and give us what we need to start the process of remediation …*[102]

10.106 Dr Moyes told the Inquiry that at this point:

> *I had no doubt that Monitor could justify intervention based on a report by the HCC into only parts of the Trust, but Monitor needed an assessment from the HCC which provided some conclusions rather than being expressed as incomplete. As a public body, Monitor was required to behave reasonably. I was rapidly losing confidence in the Trust at this point …*[103]

10.107 He wanted the HCC to make a recommendation to Monitor:

> *… what I wished the Healthcare Commission to do was to acknowledge that too and to say to us, "Take special measures and these are they". I still think Parliament's intention was that this is how the system would work. But as I've also acknowledged, with the benefit of hindsight one can take a different view. Perhaps if I were doing it today I would take a different view.*[104]

10.108 However, he confirmed that, at that point, Monitor had enough evidence to intervene.[105]

101 YM/25 WS0000040965
102 WM/23 WS0000040049
103 Moyes WS(2) WS0000039661, para 93
104 Moyes T93.93; see also Lavelle T91.114–116
105 Moyes T93.93

1 August 2008 – Briefing from Price Waterhouse Coopers

10.109 On 1 August 2008, Edward Lavelle was briefed by Price Waterhouse Coopers (PWC), the consultants employed by the Trust to review its governance in the light of the ongoing HCC investigation.[106] Among the concerns they shared were the following:

- With regard to the problems in A&E, PWC found there was a "comprehensive plan" but inadequate Board challenge, accountability, resourcing, project team, evaluation or reporting.
- With regard to complaints, they found that, although there was good quality information, the divisional follow-up and analysis was "less good".
- There had been little focus on clinical audit historically and, currently, ownership and accountability needed to be embedded.
- There was a low level of engagement from clinicians in the surgical division.
- The communications strategy lacked credibility, as it consisted of releasing good news stories.
- The Board was characterised as:

 ... a nice bunch of people doing the right thing but not necessarily in the right way.

- The Chair was:

 ... not really reflecting seriousness of situation through board.[107]

10.110 Mr Lavelle reported that PWC shared the Monitor view that "firefighting" would continue if the HCC continued the investigation, rather than the cultural and strategic changes required to "deliver quality care with good governance".

Amber governance rating – August 2008

10.111 On 4 August, Monitor notified the Trust of the outcome of the annual plan review for 2008/09. It was awarded an "amber" governance risk rating, apparently owing, in part, to an inability to sign a governance declaration in relation to continuing compliance with the hygiene code.[108]

15 September 2008

10.112 Dr Moyes pursued his frustration with the HCC in a letter to Anna Walker on 15 September 2008, copied to Cynthia Bower as Chief Executive of the shadow CQC, and, possibly, to Sir David Nicholson:

106 The Trust's actions in this regard had been viewed with concern by the HCC and Heather Wood, in particular, who felt that involving PwC had the potential to divert the Trust away from addressing the HCC's concerns to instead seeking grounds for disputing them. Monitor, by contrast, welcomed the involvement of PwC as reinforcing the Trust's management temporarily (Moyes WS0000039660, para 91).
107 WM/26 WS0000040059–61
108 WM/27 WS0000040063

... I am keen to use Monitor's intervention arrangements to get an agreed action plan and to focus on ensuring effective implementation. I believe this is urgently needed to achieve our common objectives of a well governed trust delivering high quality care. But we are reluctant to do that while an HCC investigation is in progress ... My principal concern remains the diminishing benefits of continuing the current programme of investigation ...[109]

10.113 He expressed concern that the Trust's management would have a reduced capacity during the investigation to take forward necessary strategic changes while attending to operational matters raised by it.

We believe it would be in everyone's interests for the HCC to complete its investigation as soon as possible (whilst ensuring that the main concerns from the investigation have been identified and addressed) ... The board may not be able to focus on the creation of [a strategic] *plan and Monitor can't credibly begin to fulfill its role until the Healthcare Commission has concluded its work.*

10.114 Anna Walker replied on 6 October that, as yet, the HCC did not have "substantive findings";[110] while specific issues relating to A&E thought to "pose an immediate threat to the safety of patients" had been reported to the Trust for urgent action, other judgements still had to be made. The team had serious concerns about wider issues, including the Trust's governance arrangements, but was:

... still in the process of collecting the evidence to arrive at fair conclusions about those aspects of the emergency care pathway that may have, and may still be, posing a risk to patients.

10.115 She reported that the evidence collected from patients and relatives appeared to be from "highly reliable witnesses" and this had "added to our concerns." She could not justify curtailing the investigation.

10.116 Dr Moyes told the Inquiry that at this time:

... maybe with hindsight it's the wrong judgement, but I felt at the time very inhibited about using Monitor's powers of intervention when the Healthcare Commission was in the course of an investigation.[111]

109 Moyes WS(2) WS0000039663, para 99; WM/29 WS0000040069
110 WM/30 WS0000040073–4
111 Moyes T93.42

Healthcare Commission letter to Trust – 15 October 2008

10.117 On 15 October, Dr Heather Wood wrote to Martin Yeates to inform him of the HCC's continuing concerns about patient experience ahead of the draft report.[112] There were areas where it was considered that an "immediate focus" was required. These included staffing, skill-mix in and operation of the Emergency Assessment Unit (EAU), the care of traumatically injured patients, surgical out-of-hours cover and lack of protocols for unscheduled care.

10.118 Dr Moyes told the Inquiry that, during this period, he thought that the Trust's problems were "piling up" and perceived that the HCC's evidence of poor practice was mounting:

> *I understood that they were uncovering some very unpleasant things which needed to be tackled. I expected the HCC's report to be critical and I had the sense that the Trust's Board was losing control of what it needed to do, and in what order of priority.*[113]

10.119 Dr Moyes wrote to the Trust, requesting a copy of their response, and met Martin Yeates to set out what Monitor expected the Trust to do.[114]

Price Waterhouse Coopers report

10.120 On 29 October 2008, PWC sent Martin Yeates its interim report from its review of governance at the Trust.[115] Monitor had regular contact with PWC regarding its work for the Trust and were aware of its conclusions. The report highlighted concerns about the Trust's governance. These included:

- It was taking four months for a divisional governance issue to reach the Board, which was too long for significant issues. Major issues were escalated outside the reporting cycle but this led to the divisions lacking clarity on how information fed back from the Board.
- Clinicians appeared to be disengaged from the governance process, for example by not sending substitutes to meetings they could not attend.
- There was a risk of issues escaping detailed challenge because of the volume of issues and paperwork presented to the Board; it needed additional non-executive director-led sub-committees, with delegated powers to address this problem.
- The standard of presentation to the Board was variable and, on occasions, not well prepared, meaning issues might not be properly assessed.
- The standard of challenge was not consistent throughout the governance structure.

10.121 This caused Monitor further concerns, which it highlighted in a meeting with Mr Yeates and Mrs Brisby on 17 November 2008.[116]

112 WM/31 WS0000040077
113 Moyes WS(2) WS0000039664, para 102
114 Moyes WS(2) WS0000039665, paras 103–104; WM/32 WS0000040083–4; WM/34 WS0000040088
115 Moyes WS(2) WS0000039666, para 105; WM/35 WS00000040090–5
116 Moyes WS0000039666, para 107

19 November 2008

10.122 On 19 November 2008, Dr Moyes recorded in a memo that he had been told by Anna Walker that Martin Yeates would "bear the brunt of the criticism", as the Chief Executive throughout the period when the hospital was not delivering a satisfactory level of performance.[117] He had pointed out to her that the same could be said of a number of other Board members and staff. To point the finger at one individual, he felt the HCC had to be clear that that individual was uniquely responsible for the problems the hospital had experienced. Dr Moyes sensed that the report was still in flux.[118]

Monitor's expectations – 27 November 2008

10.123 On 27 November 2008, Dr Moyes wrote to Martin Yeates,[119] setting out Monitor's expectations for the Trust Board in exercising its responsibility for the design, ownership and delivery of plans to rectify the issues identified by the HCC and PWC. Monitor would hold the Board accountable for effective implementation of such plans and for putting in place processes by which the Trust would comply with its authorisation in future. The Trust would be expected to be meeting its A&E target by the end of December. Measures to be taken by the Trust would have to be agreed with Monitor and the HCC. Formal meetings would be reinstated if the steps taken were not satisfactory, as well as consideration of whether the Trust was likely to be in significant breach of its authorisation.

10.124 Dr Moyes explained that he wanted the HCC to provide clear statements which could be used to establish if there were breaches of the terms of authorisation, rather than further detail which would not affect that decision. It was not, he believed, for Monitor to prescribe detailed remedies, such as staffing levels, because that would lead to Monitor assuming responsibility for decisions which were for the Trust to take.[120]

General comments on intervention

10.125 In October 2009, Dr Moyes, writing to the DH, was heavily critical of the HCC, suggesting it was the HCC's failure to conclude the investigation quicker that led to a delay in Monitor's intervention:

117 Moyes WS0000039667, para 109; WM/38 WS0000040103
118 WM/38 WS0000040103
119 WM/39 WS0000040106
120 Moyes WS(2) WS0000039667, para 110

The main problem at that stage, in my view, was the Healthcare Commission's process. The investigation took too long and was too geared to establishing evidence to secure "a conviction". I repeatedly pressed Anna Walker to bring the investigation to a much earlier conclusion once it was clear that there was enough evidence to justify intervention and changes at board and senior management level, but this wasn't something the Healthcare Commission was prepared to do. And we felt very inhibited about using our formal powers of intervention before the Healthcare Commission had concluded its investigation and produced its report.[121]

10.126 He repeated this criticism to the Inquiry. He saw no reason why the HCC could not have recommended that Monitor intervene while continuing its inquiries, although he accepted that the HCC did not explicitly request Monitor not to do so.[122]

10.127 Dr Moyes defended Monitor's policy of not deciding on intervention until the HCC report was published and maintained the view that it would have been better for the HCC to have finished its investigation more speedily to provide the basis for intervention:

... if we had intervened and then it had emerged that actually the Healthcare Commission weren't finding that much and a lot of it was either not very serious or being put right, I probably would have been sitting here defending jumping the gun. So you make a judgement at the time, in the circumstances of the time, and the judgement I made at the time, and I think my board colleagues shared at the time, was that when an investigation of this seriousness is under way – I mean, Healthcare Commission investigations didn't come along every week, this was a very unusual occurrence. When something of this seriousness was under way, for Monitor to rush in and use its powers of intervention ... was inappropriate. As I say, maybe with the benefit of hindsight I got it wrong.[123]

10.128 He argued that the proper course was to wait for the HCC to recommend intervention:

With due respect, in the legislation I don't think that it is my judgement or Monitor's judgement to say this hospital needs special measures. I think the way the legislation was set up, as I understood it at the time, was that the Healthcare Commission could have come to us at this point, and said, "We have done enough work to conclude that special measures are needed and we invite you to get the trust to do the following things".

Q. Well, they could have done, but if they don't, was Monitor powerless?

121 WM/104 WS0000040382; Moyes T93.81
122 Moyes T93.89–92
123 Moyes T93.44

A. Well, I felt at the time, and you may say now that I took the wrong decision and that I didn't advise my board properly, but I did feel at the time that with a Healthcare Commission investigation that was continuing, that had not reached conclusions, we didn't have a formal conclusion from the Commission itself, that it was very difficult for Monitor to use its formal powers of intervention ... with the benefit of hindsight, I might agree with you that it would have been better if I'd said to the board, "Let's take our courage in our hands and intervene, and if we're criticised for intervening while an investigation is ongoing, we'll deal with it". But at the time, it just did not feel the appropriate thing to do.[124]

10.129 He explained that there had been a fear that, if an intervention had been decided upon but could not then be justified, Monitor would have been vulnerable to judicial review.[125] This would have led to a relationship of confrontation with the Trust, and Monitor would have lost its power to influence it. He was fearful that would not have benefited patients.[126]

10.130 He accepted that if Monitor had concluded that it had been misled in the course of the authorisation process that would, in itself, have been grounds for intervention. Indeed, he told the Inquiry that an intervention had previously taken place at another FT on precisely that ground. Monitor did come to a similar conclusion in relation to the Trust, but only, it appears, after the publication of the HCC report.[127]

10.131 He accepted that, in hindsight, it could be argued that Monitor was overcautious over the possibility of judicial review and conceded that, subsequently, Monitor had intervened more frequently, even though this had provoked more challenge. There had, in fact, been no successful challenge to Monitor in relation to an intervention.[128]

10.132 Stephen Hay, Chief Operating Officer at Monitor, told the Inquiry that, until learning the lessons from the experience of Stafford, it had not been clear to either Monitor or the HCC which organisation was examining how a trust board assured itself of quality of care. He said that that issue had now been addressed.[129] However, Monitor had always recognised that it was part of its role to check that the board was doing its job properly. In his view:

A well run hospital should not suffer the kinds of problems identified at the Trust, and while it is not Monitor's role to oversee clinical performance, it is responsible for ensuring that the board of each trust identifies and resolves clinical issues.[130]

124 Moyes T93.72–73
125 Moyes T93.44–45
126 Moyes T93.85
127 Moyes T93.51–53
128 Moyes T93.86
129 Hay WS0000041196, para 7
130 Hay WS0000041196, para 6

10.133 Edward Lavelle thought that, even in retrospect, Monitor had been effective in performing its regulatory compliance function in relation to the Trust between March 2008 and the end of 2009, although he accepted there were lessons to be learned.[131]

Monitor's reaction to the Healthcare Commission's draft report

10.134 Dr Moyes was first sent a draft extract of the HCC's report on 18 December 2008. He was required to sign a confidentiality undertaking, which he regarded an unacceptable requirement between regulators, but to which he acceded for pragmatic reasons.[132] He was sent a part referring to the Trust, rather than other health service organisations, without any conclusions, recommendations, executive summary or lessons to be learned.

10.135 Dr Moyes prepared a note of his thoughts on the draft on 9 January 2009. He was concerned that it did not:

> *... provide as strong an evidential picture of what was happening at the Trust as it might.*[133]

10.136 Dr Moyes offered a detailed critique of the drafting of the report: he was concerned at the amount of hearsay, the sources of which were not identified. He was confident that the HCC had the evidence to prove its findings but thought it was important that it be included in the report in order that Monitor could make a decision on the exercise of its statutory powers.

10.137 These thoughts and analysis were transmitted to Dr Heather Wood in a letter of 12 January 2009.[134]

10.138 One of the critical comments made concerned the reliance on information from patients and relatives:

> *... this was a group of people who responded to an invitation from the Healthcare Commission and therefore was a self-selecting group. We and the Healthcare Commission would have to exercise great care in any conclusions we may draw from the comments made by a group which may not provide a fair representation of patients.*[135]

131 Lavelle WS0000036221, para 120; T91.181–2
132 Moyes WS(2) WS0000039667–8, para 112; WM/40 WS0000040110
133 Moyes WS(2) WS0000039668, paras 113–114; WM/41 WS0000040113–6
134 Moyes WS(2) WS0000039668, para 115; WM/42 WS0000040118
135 WM/42 WS0000040121

10.139 Dr Moyes explained that what he intended to convey was a need to take into account positive improvements made by the Trust to deflect criticism, that what this group of patients had complained about had been remedied and that he was not seeking to undermine the force of what the group had to say.[136] Dr Moyes accepted that he was by now convinced there had been a significant breach but considered that it was important, for legal reasons, to keep an open mind.[137]

10.140 On 23 January 2009, Dr Moyes met Martin Yeates and warned him that the Trust could be in significant breach but no conclusion had yet been reached. Mr Yeates complained that the draft of the report he had seen lacked balance, even if it could not be factually challenged in many areas. He asserted that many improvements had been made and that, in some respects, the report was out of date. Dr Moyes assured him that Monitor did not intervene for the sake of it.[138]

10.141 On 30 January, Monitor received the draft report, now including an executive summary and recommendations.[139]

10.142 On 13 February, Dr Moyes expressed doubts to colleagues about the strength of the HCC report in an email:[140]

> *Although* [Anna Walker] *expresses confidence that sound evidence exists and that the issues are matters of presentation, I'm not so sure. I'm not convinced that the HCC has a good methodology that produces strong enough evidence to satisfy a court, if it came to that. We shall see.*

10.143 He expressed an assumption that the Trust's performance on "everything else" was "back to normal", as:

> ... [t]*his would not be a good time for the trust to be failing key targets.*

10.144 Dr Moyes explained to the Inquiry that he was intending to convey "slight apprehensions" that some statements in the draft report were "not derived from firm evidence that could be produced if necessary". However, he did find the final report, when produced, to be "very satisfactory"[141].

136 Moyes T93.119
137 Moyes T93.121
138 Moyes WS(2) WS0000039670, para 118; WM/45 MON00030000746–749
139 WM/46 WS0000040136
140 Moyes WS(2) WS0000039671, para 122; WM/49 WS0000040146
141 Moyes T93.123–124

10.145 In this email, Dr Moyes predicted that Monitor would come under pressure from the DH to take action when the report was published. He told the Inquiry that David Flory, Director General of NHS Finance, Performance and Operations at the DH, had suggested to him that it would be helpful for Monitor to know in advance of publication what action it was going to take.[142]

10.146 On 20 February, Dr Moyes wrote to Mrs Toni Brisby setting out how Monitor proposed to consider what, if any, regulatory action it would take in response to the HCC report when published.[143] If Monitor's Board was to determine that the Trust was in significant breach of its authorisation, or had been and risked doing so again, it would consider the following questions in deciding what action to take:

> *Is the Trust Board taking all reasonable steps to ensure rectification of the issues in a timely and effective manner?*
>
> *Has the Trust designed and is it implementing plans, which are unlikely to remedy the issues identified in the HCC's investigation?*
>
> *Does the Trust Board have the skills, management capacity and governance arrangements in place to demonstrate that it is likely to deliver the rectification plans within an acceptable time frame?*

Contact with Martin Yeates

10.147 On 26 February 2009, Dr Moyes talked to Martin Yeates by telephone.[144] By this point, Dr Moyes told the Inquiry, he had concluded that Monitor's Board would have to make a decision on regulatory intervention very rapidly after publication. Mr Yeates told him that he, Mrs Brisby and the Trust were under increasing pressure. He said:

> *He had heard there was a lot of ministerial interest in this and the view was that if he resigned in advance of the report they could offer him another post somewhere but that if he didn't and was forced to go after the report is published, they would not be able to "save him".*[145]

10.148 Dr Moyes reminded Mr Yeates that he was Chief Executive of an FT and that the DH had no remit over him. Mr Yeates acknowledged this, but he said he needed to consider his own future.

142 Moyes WS(2) WS0000039672, para 123; Moyes T93.126–127
143 WM/51 WS0000040151–2
144 Moyes WS(2) WS0000039675–6, paras 133–135; Moyes T93.129
145 WM/53 WS0000040157

10.149 Dr Moyes then told Mr Yeates of the discussion at a recent Monitor Board meeting and that:

> *At the moment the Trust is probably in significant breach although no decision would be made until after receipt of the final HCC report, PwC report and response from the trust.*
>
> [The] *Board's current feeling is that Monitor should use statutory powers to intervene.*[146]

10.150 Dr Moyes advised Mr Yeates that, if that was the case, an Interim Chair would be appointed immediately, and that Monitor would take a detailed oversight of the action plan and would supervise the appointment of a permanent Chair, but currently Monitor had no intention to direct the Interim Chair to take any specific steps. He:

> *... noted that Monitor was not currently thinking of replacing the* [Chief Executive].[147]

10.151 Mr Yeates indicated that he would have to consider the discussions about him resigning in advance, in the light of what Dr Moyes had said.

10.152 Dr Moyes explained to the Inquiry that he had understood from conversations with Mr Yeates and Peter Shanahan, now Acting Chief Executive of the WMSHA, that if Mr Yeates wanted to stand down before the publication of the report, the SHA would find him another position, but not if he stayed on. Dr Moyes felt, at the time, that it would be dangerous to replace the Chair and the Chief Executive at the same time and was open to the idea of retaining Mr Yeates for a period, such as three months.[148] He did not continue to have confidence in Mr Yeates, and probably thought he had misled Monitor,[149] but he was concerned that, if both senior leaders of the Trust left at the same time, Dr Manjit Obhrai, who had just been recruited as Medical Director, might decline to take up his post. Encouraging Mr Yeates to stay, therefore, was:

> *... a strategy to try and make sure that we didn't take too many risks with the trust.*[150]

10.153 He was asked to explain to the Inquiry why the initial focus was on the accountability of the Chair, rather than the Chief Executive who had been responsible for running the Trust. He said:

146 WM/53 WS0000040157
147 WM/53 WS0000040157
148 Moyes WS(2) WS0000039675, paras 133–135; Moyes T93.129
149 Moyes T93.140
150 Moyes T93.131

... our developing view in Monitor was that where there is a significant failure in the organisation, you expect the chair and the board to have enough information and to be challenging enough to spot that failure and to tackle it. So one can obviously make different arguments, but the view we had come to was that the first deficiency in any organisation that's in any kind of serious situation is a deficiency in the board. Either they haven't known or they haven't asked the right questions or they haven't taken the right action.[151]

10.154 On 27 February 2009, Dr Moyes spoke to Mrs Brisby about the Monitor Board's thinking with regard to her position and the Trust. He, in effect, told her that it was almost certain that the outcome of a formal intervention would be that she would be asked to step down. Dr Moyes did not demur from the proposition that this was the equivalent of handing her a revolver and a bottle of whisky.[152]

10.155 Mrs Brisby indicated that she thought the HCC report was "rubbish" but would reflect on her position.[153] On 2 March, she indicated in a conversation with Dr Moyes that she had decided to resign and planned to do so the following day. She also understood that Mr Yeates was intending to do the same thing.[154]

10.156 By this time, Dr Moyes had identified David Stone for appointment as the Interim Chair and "behind the scenes" was in discussions about recruiting Eric Morton as Interim Chief Executive if the need arose.

10.157 Immediately after talking to Mrs Brisby, recommendations were drafted for the Monitor Board, which were to find that the Trust was in significant breach because of the imminent resignation of the Chair and Chief Executive. The Board was to exercise its formal powers to appoint Mr Stone as Interim Chair and to instruct the Trust to appoint as Interim Chief Executive such person as Monitor might direct.[155]

10.158 On the same day, Dr Moyes spoke again to Martin Yeates, who told him he was undecided whether or not to stay in post. He was apprehensive whether he could withstand local pressure and that the Interim Chair might be more demanding. He had been thinking he would stand down but was now prepared to meet Mr Stone and would not take a final view until then.[156]

151 Moyes T93.139
152 Moyes T93.137
153 Moyes WS(2) WS0000039676, para 136; WM/54 WS0000040161
154 Moyes WS(2) WS0000039676, para 137; WM/55 WS0000040163
155 Moyes WS(2) WS0000039677, para 140; WM/57 WS0000040170
156 Moyes WS(2) WS0000039678, para 142; WM/58 WS0000040172

10.159 On 3 March 2009, Monitor issued a formal intervention notice to the Trust in the terms described above.[157] The notice stated that the grounds for finding that there was a significant breach included the information made available by the HCC, PWC and the Trust itself, as well as the likely impact of the resignation of the Chair and the "imminent departure" of the Chief Executive.

10.160 There ensued some confusion over the departure of Mr Yeates. By 9 March, Dr Moyes was noting that, although Mr Yeates was no longer on the premises, he had not formally resigned as Chief Executive. Dr Moyes speculated that this was because he was seeking to receive a guarantee of alternative employment from the WMSHA. He wanted reassurance that Eric Morton was formally in place as Chief Executive.[158] Dr Moyes did not think it surprising that Mr Yeates was seeking to protect his position in this way but thought it was regrettable that the WMSHA had "dangled" the possibility of another job in front of him.[159] He thought that where a chief executive had "manifestly failed", as he believed the case to be here, it was a mistake to offer him the possibility of employment elsewhere.[160]

10.161 On 10 March, Dr Moyes took part in a meeting with the then Secretary of State, the Rt Hon Alan Johnson MP, in which Anna Walker and Sir Ian Kennedy (Chief Executive and Chair of the HCC respectively) also participated. Dr Moyes gave evidence that Mr Johnson "instructed" the HCC to remove reference to a range of numbers of avoidable deaths from the report.[161] In his oral evidence, he made it clear he did not mean a formal instruction had been given, but that the Secretary of State had expressed a strong view. As is clear elsewhere in this report, it is accepted that Sir Ian came to his own, independent decision that the numbers should be excised from the report.

10.162 The HCC report was formally published on 18 March 2009. Dr Moyes wrote immediately to David Stone requiring the Trust to consider all aspects of the report with care and to reflect on its recommendations. He made it clear that Monitor was prepared to use its powers again to ensure the quality and safety of patient care at the Trust, if it thought this necessary.[162]

KPMG report

10.163 Following the publication of the HCC report, Monitor's Board decided to commission an external review by KPMG of its performance in the case of the Trust (both in relation to the assessment of its application and Monitor's interaction with the Trust as regulator following the Trust's authorisation) and to draw out the lessons to be learnt.[163] Among its conclusions were:

157 WM/59 WS0000040175–7
158 Moyes WS(2) WS00000396815, para 150; WM/64 WS0000040206
159 Moyes T93.133
160 Moyes T93.134
161 Moyes WS(2) WS0000039681–2, para 152; Moyes T93.146–147
162 Moyes WS(2) WS0000039683–4, para 156; WM/66 WS0000040214
163 Moyes WS(2) WS0000039686, para 165

- Quality governance was not reviewed systematically by either Monitor or the HCC.
- In relation to its decisions whether or not to intervene, while the final decision had been clearly documented, earlier ones not to intervene had not been.
- At the time of the publication of the HCC report, Monitor was engaged in intervention at another Trust. KPMG felt it had limited senior management capacity to deal with multiple interventions.[164]
- Because the Executive Chair, Dr Moyes, was heavily involved in discussions regarding the Trust from March 2008 until the intervention took place, it was not possible for him to stand back and take a broader view of the needs of stakeholders as well as taking part in the operational aspects.
- Monitor's clinical managerial experience and expertise was limited to two Non-executive Directors; there was no such experience in the assessment and compliance teams.[165]
- While Dr Moyes was able to identify an Interim Chair and Chief Executive for the Trust from his own contacts, there was no formal process to identify such people.

10.164 A large number of recommendations were made:[166]

- Stronger reassurance on quality should be obtained during the assessment.
- There should be a stronger focus upon quality and clinical governance.
- Quality and clinical governance thresholds in compliance should be redefined.
- Stakeholder information flow should be enhanced to help assess compliance against new thresholds.
- An evaluation of the impact of FT plans upon clinical risks should be undertaken so that where significant cost reduction is planned, this is highlighted as a potential risk.
- Monitor should have access to clinical management skills, although not necessarily through creation of a post or posts for that purpose.
- The level of assurance obtained on clinical data and clinical governance needed to be increased.
- Documentation on interventions needed to be improved, and, in particular, decisions not to intervene should be documented.
- Centrally maintained documentation of events at issue trusts required enhancement.
- The level of engagement with FT governors should be increased.
- The capacity of the senior management structure and skills should be strengthened by including clinical management skills.
- A senior management figure should be assigned the role of independently challenging decisions on intervention.
- A process for the recruitment of interim chairs and chief executives needed to be established.

164 BM0001000153, *Learning and implications from Mid Staffordshire NHS Foundation Trust* (5 Aug 2009) KPMG
165 BM0001000153, *Learning and implications from Mid Staffordshire NHS Foundation Trust* (5 Aug 2009) KPMG
166 Miranda Carter WS00000030606–8, paras 78–80; Masters WS0000035329–33, para 47

10.165 Monitor accepted a number of the criticisms and pledged to take action to resolve them.[167] Some of the key points were:

- Significant weight would be placed upon the advice and judgements of the CQC in order to avoid duplicating regulatory roles. Written assurance would now be sought from the CQC and the DH prior to authorisation being granted;
- The authorisation threshold for trusts with regard to quality performance would need to be periodically revised;
- Monitor would need to enhance its approach to assurance on whether a trust's board is adequately carrying out its role in ensuring good clinical governance.

10.166 Subsequently, Monitor changed its working practices to implement these points and, in particular, to ensure that it meets with the CQC as well as the local SHA and PCT in order to obtain assurances as to the quality of the services being provided at trusts applying for FT status.[168] It has also sought to assess the impact of cost improvement plans on quality, and has created a panel of external quality advisers to challenge Monitor on its findings.

10.167 In August 2010, Monitor published a progress report on its implementation of the KPMG recommendations. This stated that:[169]

- From January 2010 onwards, in relation to each FT application, Monitor had received a formal letter from the DH confirming the date when the Secretary of State made the decision to support a trust's application and that they were not aware of any further matters since that date that may have materially affected the Secretary of State's decision. Any issues raised in the letter obtained from the DH or the CQC were likely to delay an authorisation decision;
- The quality bar for authorisation had been redefined to incorporate the CQC's registration standards, the Secretary of State's gateway threshold and Monitor's governance risk rating;
- From April 2010, applicant trusts have been required to demonstrate that they are registered with the CQC without compliance conditions and that they continue to meet the quality threshold set by the DH at the time of Secretary of State referral. Furthermore, the CQC's current judgement of compliance against registration at the time of the application must show: the overall level of concern to be no worse than moderate with high confidence in capacity; that the CQC is not conducting or about to conduct a responsive review; and that no enforcement or investigation activity is ongoing. They must have a governance risk rating under the compliance framework of no worse than amber-green;
- A Memorandum of Understanding had been agreed with the CQC which underlines the significant weight placed by Monitor upon the CQC's assurance that essential standards of quality and safety are being met and that services are safe;

167 Miranda Carter WS00000030606–8, paras 78–80; Masters WS0000035329–33, para 47
168 Hill WS0000037934–5, paras 114–115
169 AM/12 WS0000035853

- When assessing the board's role in assuring "clinical" governance, the term "quality" governance would be adopted, following the definition of "quality" in Lord Darzi's report *High Quality Care for All,*[170] quality governance being the combination of structures and processes at and below board level to lead on trust-wide quality performance;
- A team of assessors would then assess and evaluate the quality governance arrangements at applicant trusts;
- A key area of assessment would be the potential implication of Cost Improvement Plans (CIPs) on clinical quality. Boards would be required to provide evidence of how they monitor and understand current and future risks to quality and take steps to address them;
- Revised board-to-board packs had been developed to include further detail of the impact of CIPs upon headcount and how applicants monitor CIPs for their impact upon quality;
- Rather than recruiting clinical advisers to the assessment team, Monitor was to develop a network of expert advisers including access to clinical and nursing skills and DH intensive support teams;
- The compliance framework would now incorporate an outline of the escalation and intervention process;
- Decisions by the Board not to intervene following a significant breach of the terms of authorisation would be minuted and published;
- Each FT must now designate a lead governor to liaise directly with Monitor.

Current compliance practice

10.168 Monitor continues not to be responsible for performance-managing FTs, a role which is the sole preserve of an FT board, so long as there is compliance with the terms of authorisation.[171]

10.169 Monitor has a scale of risk rating for quality governance (green, amber, red), and "amber" and "red" ratings provoke an escalating level of interest from Monitor. It is not clear the extent to which this is a role which Monitor is yet equipped to take on completely effectively. It was not one it undertook when the HCC was the healthcare system's regulator:

> *As the HCC carried out this role, we never considered it to be Monitor's task to make an independent assessment of the quality of care offered either by an applicant or an existing foundation trust.*[172]

10.170 Monitor witnesses expressed confidence that current practice would detect another Stafford, largely because of the approach to quality governance and improved coordination between regulators. In particular, more attention is paid to trends in complaints and patient concerns.[173]

170 *High Quality Care for All: NHS next stage review final report* (June 2008) Department of Health, www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085825
171 Bennett WS0000030517–8, para 9; Lavelle T91.33; CLO0000022010, Counsel to the Inquiry's closing submissions, *Chapter 14: Monitor*, paras 305–308
172 Masters WS0000035313, para 8
173 Hill WS0000037935, para 117; Lavelle WS0000036217–8, paras 108–109

Current position

Duty in relation to quality

10.171 Under the new reforms, Monitor will continue to regulate NHS foundation trusts but the process of authorisation will be replaced by a new licensing regime. In addition, it will have the power to license providers of NHS funded services in England, including but not limited to FTs.

10.172 It will also become the sector regulator for healthcare. It will use its powers in this regard to manage:

> *... key aspects of health care regulation including, regulating prices, enabling services to be provided in an integrated way, safeguarding choice and competition; and supporting commissioners so that they can ensure essential health services continue to run if a provider gets into financial difficulties.*[174]

10.173 Monitor's main duty is:

> *... to protect and promote the interests of people who use health care services by promoting provision of health care services which –*
>
> *(a) is economic, efficient and effective, and*
>
> *(b) maintains or improves the quality of the services*[175]

10.174 Monitor is required, in exercising its functions, to have regard to:

> *... the need to maintain the safety of people who use health care services ...*

and

> *... the desirability of securing continuous improvement in the quality of health care services ...*

and

> *... the need for high standards in the education and training of health care professionals.*

174 *Introduction to Monitor's Future Role,* (20 June 2012) Monitor www.monitor-nhsft.gov.uk/monitors-new-role; www.legislation.gov.uk/ukpga/2012/7/part/3/chapter/3
175 Health and Social Care Act 2012 section 62(1), www.legislation.gov.uk/ukpga/2012/7/contents

10.175 It must also have regard to any guidance issued by the Secretary of State in relation to the improvement of the quality of services.[176]

10.176 It is obliged to:

> *... obtain advice appropriate for enabling it effectively to discharge its functions from persons who (taken together) have a broad range of professional expertise in ... the prevention, diagnosis or treatment of illness.*[177]

10.177 It is required to carry out impact assessments in relation to any proposal which it considers likely to have a significant impact on persons who provide or use health services, among other circumstances. Impact, although not expressly defined, must include potential impact on the quality of a service.[178]

10.178 With regard to Monitor's new licensing powers, it is intended that FTs will be granted a licence automatically one year before other providers.

10.179 It is proposed that the licence will contain a requirement that governors and directors be fit and proper persons.[179] This is considered further in *Chapter 24: Leadership in healthcare*.

10.180 The other general licence conditions, applicable to all licensees, are currently proposed to include:

- An obligation to provide Monitor with the information it requires for its licensing function;
- An obligation to publish information as required by Monitor;
- An obligation to have regard to Monitor's guidance;
- Some form of requirement to have a system for complying with licensing conditions;[180]
- Registration with the CQC;
- Publication of transparent patient eligibility and selection criteria;
- An obligation to carry out its activities "effectively, efficiently and economically".

176 Health and Social Care Act 2012 section 62–63, www.legislation.gov.uk/ukpga/2012/7/contents
177 Health and Social Care Act 2012 section 62(8), www.legislation.gov.uk/ukpga/2012/7/contents
178 Health and Social Care Act 2012 section 69, www.legislation.gov.uk/ukpga/2012/7/contents
179 *The New NHS Provider Licence: Consultation document* (31 July 2012) Monitor, www.monitor-nhsft.gov.uk/sites/default/files/The%20new%20NHS%20provider%20licence%20consultation%20document%20final%20-%20310712%20PDF_0.pdf page 15
180 *The new NHS Provider Licence: Consultation document* (31 July 2012) Monitor, www.monitor-nhsft.gov.uk/sites/default/files/The%20new%20NHS%20provider%20licence%20consultation%20document%20final%20-%20310712%20PDF_0.pdf, page 22. Currently Monitor's preference is for a requirement for "appropriate" systems to be in place and for self certification for this.

10.181 FTs will be subjected to some additional requirements, including:

- Compliance with any request for information from the advisory panel for governors mentioned above;[181]
- A requirement to ensure the existence of appropriate arrangements to provide representative and comprehensive governance in accordance with the Act and to maintain the organisational capacity necessary to deliver the mandatory goods and services and the mandatory education and training.

10.182 The elements of governance to be required are represented in table 10.1, taken from Monitor's consultation document:[182]

Table 10.1: Components of governance.

Area of governance	Summary of the licence condition's requirements
Board leadership	The board provides effective leadership through appropriate board structures and committees, clear responsibilities and lines of accountability – including appropriate levels of challenge and performance oversight. Business planning and other strategic decision-making processes are rigorous and robust.
Organisational management	The licensee has systems in place to ensure the provision of accurate and timely information, and operates effective systems of performance management and risk assessment. Where issues or risks are identified, they are appropriately escalated. The licensee's internal processes and structures are sufficient to ensure ongoing compliance with the licence, health care standards and legal requirements. Systems of financial oversight and controls are sufficient to ensure the licensee can remain a going concern.
Quality governance	The licensee's governance systems ensure effective oversight of the quality of care provided. This includes incorporating sufficient quality expertise at board level, and ensuring that quality considerations are appropriately reflected in business plans. In addition, the licensees should be able to monitor quality of care effectively, taking timely and appropriate action to address issues and listening to stakeholders, where necessary.
Capability	The licensee should have systems in place to ensure there is sufficient capability at all levels to secure compliance with its licence.
Validation	The licensee can confirm current and future compliance with the licence through: (i) statements to Monitor, including assessments of forward risk to compliance and actions to address this risk; and (ii) demonstrating that its auditors are satisfied that all such actions have been taken.

10.183 Monitor is considering the use of various approaches to assess FTs' governance as shown in table 10.2, also taken from the consultation document:[183]

181 *The New NHS Provider Licence: Consultation document* (31 July 2012) Monitor, www.monitor-nhsft.gov.uk/sites/default/files/The%20new%20NHS%20provider%20licence%20consultation%20document%20final%20-%20310712%20PDF_0.pdf, p56
182 *The New NHS Provider Licence: Consultation document* (31 July 2012) Monitor www.monitor-nhsft.gov.uk/sites/default/files/The%20new%20NHS%20provider%20licence%20consultation%20document%20final%20-%20310712%20PDF_0.pdf, p69–70
183 *The New NHS Provider Licence: Consultation document* (31 July 2012) Monitor, www.monitor-nhsft.gov.uk/sites/default/files/The%20new%20NHS%20provider%20licence%20consultation%20document%20final%20-%20310712%20PDF_0.pdf, p70–71

Table 10.2: Approaches to assessing the governance of foundation trusts

Examples of oversight mechanisms	Regulatory considerations
Proxy measures	Monitor currently uses performance against a set of healthcare targets and indicators as a proxy for governance at NHS foundation trusts and we are considering continuing this. The healthcare targets and indicators are currently drawn from the NHS Operating Framework. According to the 2012 Act, the Secretary of State may publish on objectives specified in the mandate that he issues to the NHS Commissioning Board which he considers relevant to Monitor's exercise of our functions. Hence Monitor would consider measures specified in that mandate in setting proxies for governance. Where an NHS foundation trust's overall performance against these metrics gives Monitor **reasonable grounds** to consider the trust may be in breach of, or at risk of breaching, the governance licence condition Monitor may take action. This could take the form of a triggered review of governance (see below), the imposition of another licence condition or use of other formal enforcement powers.
General monitoring	While we have identified a number of specific indicators for assessing compliance with the governance condition above, we may also consider whether, in the round, other factors may represent a breach, or potential risk of breach of the condition. Where Monitor reasonably believes that this is the case we may consider taking action. This could take the form of a triggered review of governance (see below), the imposition of another licence condition or use of other formal enforcement powers. We do not consider such triggers would present themselves often, but these could include, for example, the CQC warning notices, major transactions or significant reputational issues.
Triggered reviews	Where trusts are in significant breach of their terms of authorisation Monitor has in the past used its powers of direction to require governance reviews. We are considering whether, where we have **reasonable grounds** to conclude that a breach of the governance licence condition occurred, or will occur, Monitor should review the governance of the trust in question. This may comprise a review of general governance, quality governance or both. Where the findings of such reviews provide sufficient evidence to conclude that a foundation trust has breached, or is failing to take sufficient steps to reduce the risk of a breach of condition, Monitor may subsequently choose to take action. Monitor has a number of powers to address licence breaches. The findings of such a triggered review would inform the actions taken.
Regular reviews	As part of overseeing compliance with the governance condition, we are also considering a regular review of governance – i.e. every 3–4 years – at NHS foundation trusts. Governance issues may arise at foundation trusts several years after authorisation. A re-assessment of the governance of a foundation trust at a suitable interval after its authorisation would not only allow Monitor to assess compliance with the governance licence condition directly but also a further level of forward assurance. As with triggered reviews above, where the findings of such reviews reasonably indicated a breach, or risk of breach, of the licence, Monitor may subsequently choose to take action. Monitor has a number of powers to address breaches of the governance licence condition, and the findings of such a review would inform the actions taken.
Audit	Monitor currently requires NHS foundation trusts to include specified content in their Annual Governance Statements. This content includes processes to secure good financial and quality governance. Monitor also currently requires auditors to provide a limited assurance opinion on the Annual Governance Statement (i.e. the auditors are not aware of any evidence that would suggest the Annual Governance Statement is not a true and fair view) We are considering broadening the scope of such work by: • Requiring NHS foundation trusts to produce, at the beginning of each year, a document confirming current and forward expected compliance with obligations including any actions to address risks to this; and • Requiring the auditors at the end of each year to give a limited assurance opinion on whether any actions have been carried out. Where opinions are qualified, Monitor could then take further action to determine whether the NHS foundation trust is in breach of the governance condition.

10.184 Thus, Monitor intends to continue to interest itself in the provision of a clinical as well as a financial governance system and, in particular, has indicated it will expect FTs to be able to monitor quality of care "effectively" and take "timely and appropriate" remedial action, as well as to listen to stakeholders. It intends to assess compliance by measures which will include proxy measures such as the healthcare targets and indicators in the NHS Operating Framework, the NHS Mandate, and general monitoring of matters such as CQC warning notices and "significant reputational issues".

10.185 Monitor has also given an indication of the form to be taken by its risk assessment framework. It recognises that a purely financial assessment

> *... may not capture other important factors and may over or understate the financial position of a provider.*[184]

10.186 Such factors include clinical or governance events which could signal an increased likelihood of future financial difficulties. Monitor emphasises, however, that it is not its role to set clinical standards, and it does not believe it would be acceptable to have clinical events form part of the framework directly, as this would amount to "trading off" clinical and financial factors. Therefore, Monitor intends to apply a "qualitative override" on a case by case basis, applying professional judgement and experience to assess the relevance of events to the financial prospects of the provider. It gives as an example the issue by the CQC of a notice of a major concern relating to a requirement to have adequate levels of staff, which could have a large impact on its financial position.[185]

10.187 Monitor is, therefore, to be largely an economic regulator, overseeing competition issues and authorising mergers, partnerships and other similar arrangements.

10.188 In his evidence, Dr David Bennett, Monitor's current Chief Executive, envisaged that Monitor's continuing role in regulating FTs' operations would become all but vestigial:

> *In summary, Monitor's current role in relation to foundation trusts will all but disappear at the end of the transition period. My expectation is that once all trusts are foundation trusts, one unit within Monitor will be carrying out the residual foundation trust regulation role, whilst the remainder of Monitor will become part of the new economic regulator.*[186]

10.189 The consultation process since then suggests that there will be a continuing role for Monitor in the regulation of FTs through the licensing system and that Monitor will concern itself with the

184 *The New NHS Provider Licence: Consultation document* (31 July 2012) Monitor, www.monitor-nhsft.gov.uk/sites/default/files/The%20new%20NHS%20provider%20licence%20consultation%20document%20final%20-%20310712%20PDF_0.pdf, p68
185 *The new NHS Provider Licence: Consultation document* (31 July 2012) Monitor, www.monitor-nhsft.gov.uk/sites/default/files/The%20new%20NHS%20provider%20licence%20consultation%20document%20final%20-%20310712%20PDF_0.pdf, p65–66
186 Bennett WS0000030536, para 60

provision by FTs of clinical governance. It will also take into account for all licensed providers clinical and governance events, such as warning notices from the CQC, but in relation to their relevance to financial sustainability.

10.190 It is intended to be the CQC which, through the registration process, will regulate the quality aspects of FTs.

10.191 The significance of these developments and how the lessons from Stafford should be applied in the context of the new regime is considered in *Chapter 11: Regulation: the Care Quality Commission*.

Public involvement

10.192 Monitor is required to secure that service users and the public are:

> *Involved to an appropriate degree in decisions Monitor makes ... (other than decisions it makes about the exercise of its functions in a particular case).*[187]

10.193 Under its original legislation, Monitor does not have any explicit requirement relating to patient and public involvement, although it does run regular public consultations on its guidance and policies. Monitor also has a duty to ensure that trusts applying for FT status have carried out a consultation as part of their application process, engaging, among others, members of staff and people in the local area.[188]

10.194 In order to prepare for its new role, Monitor has commissioned PWC to conduct a study, culminating in recommendations for how Monitor should involve patients and take account of their interests in its strategic and operational decision-making in a systematic and coherent manner. The project will also recommend steps Monitor could take to encourage health sector providers to protect and promote the interests of patients.[189]

Foundation trust governors

10.195 FT governors will in future have the power to hold the FT chair and the non-executive directors individually and collectively to account, and to represent the interests of the membership and the public interest.[190]

10.196 FTs will be obliged to take steps to provide that governors are equipped with the skills and knowledge they require to undertake their duties.[191]

187 Health and Social Care Act 2012 section 62(7), www.legislation.gov.uk/ukpga/2012/7/contents
188 National Health Service Act 2006 section 35(5), www.legislation.gov.uk/ukpga/2012/7/contents
189 Details are set out on Monitor's website at: www.monitor-nhsft.gov.uk/monitors-new-role/overview/creating-patient-focused-regulator
190 National Health Service Act 2006, Schedule 7 para 10A, inserted by the Health and Social Care Act 2012 section 151
191 National Health Service Act 2006, Schedule 7 para 10B, inserted by the Health and Social Care Act 2012 section 151

10.197 The 2012 Act will provide a power to Monitor to set up an advisory panel to which FT governors can refer a question of whether their organisation is in breach of statutory and authorisation requirements.[192] It is Monitor's intention to create such a panel.

Conclusions

Foundation Trust Boards

10.198 Dr William Moyes did not support the idea that non-executive directors of FTs should be required to have a minimum level of qualifications or accreditation for the role. His arguments against this seemed largely to centre on the perceived inability of Monitor to require the replacement of non-executive directors post authorisation, unless an FT was found to be in significant breach of its authorisation terms, because to do so would cut across the role of the governors. Part of the story of Stafford is that the non-executive directors were not, as a group, able to meet the challenges of the job of running such a large and complex organisation. Yet they, as were and are all FT boards, were considered to be the performance managers of the organisation.

10.199 The role may require the skills of a director of a large commercial organisation, but it may not be one to which it is easy to attract people of the right calibre and experience. FT non-executive directors are usually offered remuneration which will be significantly less than their counterparts in the commercial world, and the notional time commitment is likely to be unrealistic in view of the heavy responsibilities they are meant to shoulder. Governors who may themselves come from disparate backgrounds in the community, may also not be well equipped to make judgements on the necessary qualifications and experience when selecting non-executive directors or holding them to account.

10.200 It would not be inconsistent with the autonomy of FTs to take a number of steps to safeguard the public interest by ensuring not only that FTs have a competent board peopled with competent directors on authorisation, but also that they *continue* to have such a board. Measures which would help to achieve this without undue interference in the powers of governors include the introduction of a requirement that all directors of FTs are, and remain, fit and proper persons for the role. Monitor is currently considering the introduction of such a requirement as part of its licence and the use of this is discussed in *Chapter 24: Leadership in healthcare*.

- Monitor already requires, as part of the authorisation process, FT applicants to self certify that they have in place a selection process and training to ensure non-executive directors have the appropriate level of skills and experience. The standard terms of authorisation include a requirement of compliance with best practice in corporate governance. The constitution (assuming the trust's constitution is standard in this respect) has a list of

192 National Health Service Act 2006, section 39A, inserted by the Health and Social Care Act 2012 section 162

disqualifications for the post of director, but it is quite possible for a person not to be subject to disqualification but still be unfit to continue in post.[193] For example, while a person may be disqualified under an FT's constitution from being a director if he or she has been previously dismissed from an NHS post, that would not apply to Mr Yeates, who resigned under the terms of a settlement. It is not in the public interest that a regulator has to wait for a significant breach to take place before taking protective action.

- If a "fit and proper person" test were introduced, whether through the proposed licence or some other route, the regulator should issue guidance on the principles on which it would exercise its power to disqualify or remove directors who did not fulfil it and the procedure it would follow to ensure due process.
- The criteria for fitness could include a minimum level of experience and/or training, while giving appropriate latitude for recognition of equivalence. There seems no reason why demonstration of a minimum level of knowledge of matters relevant to healthcare governance should not be required.
- A finding that a person is not a fit and proper person on the grounds of serious misconduct or incompetence should be a circumstance added to the list of disqualifications in the standard terms of an FT's constitution.
- A requirement should be imposed on FTs to have in place an adequate programme for the training and continued development of directors.

Foundation Trust governors

10.201 The governors of an FT theoretically play an important role in its oversight. Their power to dismiss the chair and non-executive directors potentially gives them considerable scope to influence the running of the organisation. It is clear from the experience of the Trust's governors, and from meetings the Inquiry had with governors at a number of other FTs of varying sizes that, in practice, there are numerous challenges facing them:

- *Weakness of mandate*: Apart from any governors nominated by local representative bodies, an FT's public governors are elected by a membership which is grouped into constituencies in a variety of ways.[194] The membership is by definition a self selecting group and is not necessarily representative of the community from which it is drawn. The precise arrangements vary according to the individual constitutions of FTs as approved by Monitor. While this may be inevitable under this type of structure, and has value in enabling local conditions and needs to be recognised, it is important that governors are accountable not just to the immediate membership but to the public at large. While the requirement that governors' meetings are held in public goes some way to facilitating this, it is important that regular and constructive contact between governors and the public is maintained. In this way, governors can explain their work to the public and benefit from being open to public views of the service they are receiving.

193 CURE00330015630, *Trust Constitution*, clause 28
194 For a list of the required membership of the council of governors see National Health Service Act 2006 Schedule 7 para 9 as amended by Health and Social Care Act 2012 section 151

- *Potential lack of authority and experience*: Governors are a disparate group from a wide variety of backgrounds. While they are a valuable source of information about local views, they are unlikely to be able to assess fully the competence of the board or effectively monitor its performance unless they have adequate support, for which they are currently almost entirely dependent on the board itself. Pursuant to the obligation of FTs to provide appropriate training, steps need to be taken to enhance governors' independence and ability to bring to light and challenge deficiencies in the services provided by FTs.
- Monitor provides a level of guidance and training, and this should be encouraged and developed.
- There appears to be a lack of clarity and consistency around what the governors' role is and how it is to be performed. The Inquiry has encountered a wide range of practice, from a role not far removed from a hospital visitor, to something almost approaching the challenge expected to be undertaken by non-executive directors. Much seems to depend on the leadership given by the organisations' chairs and chief executives.
- Governors need to have their authority reinforced by ready personal access to external assistance and support, such as might be provided by their national association. This suggests that membership of such an association should be a requirement of taking up the post. Governors met during the Inquiry's healthcare visits were largely complimentary of the internal support they received from their chairs and chief executives but highlighted the need for further external support.
- The advisory panel which Monitor will set up under the Health and Social Care Act 2012[195] as a reference point for governors who fear their trust is in breach of its licence can be developed into a valuable source of support, but its remit appears to be limited to reporting its opinion on whether such breaches have occurred. Therefore, another source of advice is required to address clinical quality issues. Under the current regulatory structure the CQC could and should consider setting up a comparable panel to which governors could gain access.

Monitor's relations with the Department of Health

10.202 Dr Moyes was understandably very keen to establish and affirm the independence of Monitor and, therefore, was very keen to point out where he felt other organisations and officials overstepped the boundary into Monitor's jurisdiction. It is inevitable, so long as the NHS is dependent on public funding, that the Government will have a legitimate interest in the efficacy of the systems regulator and it would be unfortunate if constructive engagement were compromised by legalistic dispute about the precise language which should be used in communications. There is no evidence that in its dealings with Monitor generally, or with reference to the regulation of the Trust in particular, the DH acted improperly or interfered with the statutory discretion of Monitor.

195 National Health Service Act 2006, section 39A, inserted by the Health and Social Care Act 2012 section 162

Monitor's exercise of its powers of intervention

10.203 Monitor did not formally decide that the Trust was in significant breach of its authorisation until after the publication of the HCC report. However, as admitted by Dr Moyes, it had been aware since at least May 2008 that there was a likelihood that it was in significant breach. Even before then, there were substantial grounds for suspecting that there was a continuing breach. By May 2008, it was known to Monitor that the reassuring picture painted by the Trust's Board, which had been the context for the decision to authorise it only three months before, was likely to be inaccurate. There were increasing indications that the Trust Board was not addressing the growing crisis effectively and was not capable of doing so, including the Chief Executive's own admission of having been unaware of particular issues, his complaints of unfairness, and its external consultant's critical findings about the competence of the Board. It was known, from information offered by the HCC, that there were immediate concerns about patient safety. Monitor did, in the event, intervene before the publication of the report, when it became clear to it that the position of the Chair, and in reality the Chief Executive as well, was untenable.

10.204 No intervention took place because Monitor's senior management thought that it should wait for the HCC's final report or for the HCC to make interim recommendations for intervention. It did so because it took the view that, until either of those conditions were fulfilled, it lacked the evidence on which to proceed. Candidly, Dr Moyes accepted that in hindsight that judgement could be questioned.

10.205 The evidence shows that the reasoning adopted, as indicated in the evidence of Dr Moyes, was flawed. The constant complaint to the HCC that the investigation was taking too long arose out of Monitor's concern that regulatory action was required. Monitor knew, from what the HCC had said in its correspondence with the Trust, that there was a threat to the safety of patients and, from its own observation and the PwC report, that the Trust had a Board which appeared to lack the insight or the drive to address the growing number of problems confronting it. It could have, but did not, request the HCC to furnish it with an interim report presenting the evidence and any recommendations that Monitor believed to be lacking. In any event, Monitor was wrong to believe there was insufficient evidence to act. While the HCC was obliged by statute to make a report to Monitor if it found significant failings at an FT, such a report was not a prerequisite of intervention.[196] Monitor had evidence that the HCC had concluded that there was a sufficient threat to safety to require the Trust to take immediate action. The material available was sufficient to justify an immediate decision on the presence of a significant breach. Monitor became over preoccupied with a distinction between evidence and information while failing to give sufficient regard to their duty to protect patients.

10.206 Instead of taking action of its own volition, even though it believed action was necessary, it applied constant pressure on the HCC to conclude its investigation before it was ready to do

196 Health and Social Care Act 1983 section 53

so. While neither Dr Moyes personally nor Monitor generally had any intention to prevent or hinder the HCC in completing its work, this pressure could have had an adverse effect. While there may be criticism over the length of the investigation, the HCC is in fact to be commended for resisting that pressure and insisting on completing the job it set out to achieve. Had it not done so, it is likely that the full scale of the appalling situation at the Trust would not have been uncovered. Monitor was not bound to wait for the report, and it had not done so in other circumstances. There were other ways to justify definitive action by the Trust, as opposed to the "fire-fighting" which Dr Moyes quite understandably wished to avoid.

10.207 Monitor correctly considered that any intervention should be on a legally justifiable basis, but it was unduly concerned that taking action in advance of formal findings by the HCC would lead to judicial review proceedings. It was concerned that such proceedings would lead to a confrontational reaction from the Trust and delay remedial action. Yet it was faced with the very real possibility that the Trust Board would not take effective action in any event. In such circumstances, a litigation risk would have been worth taking in the interests of protecting patient safety. Whether a challenge would have been mounted might have depended on precisely what intervention Monitor decided to make. It is not inevitable that a finding of a breach requires the immediate removal of the board. As an interim measure, the Trust could have been required to take other, more temporary protective measures, such as the acceptance of a consultant appointed by Monitor, or to take specified remedial actions to be documented and reported to Monitor within a specified time. Monitor could have coordinated action by the PCT and the DH, but it appears to have been very anxious to preserve its own autonomy and separation from other stakeholders.

10.208 It is not without significance that, in the end, the formal intervention on 3 March 2009 was based, in large part, on the information made available by the HCC, even though the final report had not, at that stage, been published. This demonstrates that, at that stage, Monitor did not consider there to be any legal impediment to intervention. There had, in reality, been none earlier. The issue was one for the judgement of Dr Moyes and his Board.

10.209 It is difficult to escape the conclusion that Dr Moyes had been somewhat sceptical of the strength of evidence underlying the HCC's findings as they were reported to him.

10.210 The result of this hesitation to act was that the Trust continued, for a sustained period, to have a leadership which was deficient and unable to command confidence in circumstances where there were serious and widespread deficiencies relevant to patient safety, of which both systems regulators were aware. During that period, while individual concerns were beginning to be addressed, fundamental issues remained. Put shortly, the public remained exposed to an unacceptable level of risk. While it can be said that the HCC could have made express recommendations for action to Monitor, Monitor retained its own statutory responsibility and judgement. Insofar as it exercised these, it did so with undue delay.

Monitor's treatment of the Trust's Chief Executive

10.211 Monitor's primary focus for accountability at the Trust was the Chair, not the Chief Executive. Dr Moyes did not want the whole leadership to be dispensed with at the same time, for pragmatic reasons. He sought to persuade Mr Yeates to remain in post temporarily. It is a perfectly justifiable approach to board accountability to say that it is responsible for monitoring the performance of the Chief Executive and should be accountable for failures to do so effectively. What is less obvious is that it is safe to condone leaving in post, even temporarily, a chief executive whose performance has allowed a trust to be as deficient as was found here and in whom Monitor had no confidence. In the end, an Interim Chief Executive had to brought in more or less at the same time as the Interim Chair in any event.

10.212 Little thought was given either to the need to ensure proper accountability for any failings of the Chief Executive while in office, or to the need to ensure fairness in any procedure leading to his departure. While the Trust's contractual relations with, and the disciplining of, a Chief Executive was a matter for the Trust, Dr Moyes's communication with Mr Yeates on 26 February 2009 as described above will have given him, however unintentionally, false encouragement to stay and to pursue the possibility of alternative employment. Dr Moyes could have made it clear to Mr Yeates and, if necessary, to Mr Stone and Peter Shanahan, that his future at the Trust was to be decided entirely without reference to other employment, and that, as with Mrs Brisby, it was likely he would be expected to stand down on publication of the report. Had he done so, it is possible the dangerous confusion of Mr Yeates "stepping aside" without resigning, the resulting unfairness to him and the uncertainty as to the precise authority of the Interim Chief Executive might have been avoided. These problems might also have been avoided had he offered Mr Yeates the same opportunity to consider his position as offered to Mrs Brisby.

10.213 As has been observed in *Chapter 2: The Trust*, the circumstances surrounding Mr Yeates's departure point to the need, in the public interest, to separate the regulation of the fitness for office of a senior executive director from the commercial and pragmatic imperative in a trust to enable its business to be continued. While Dr Moyes played no part in the Trust Board's decision to negotiate a settlement with Mr Yeates, his interaction with him was comparable behaviour, in which pragmatism (in reassuring Mr Yeates that there was no intention to replace him when the intention was in fact only to leave him in post temporarily to avoid deterring a new Medical Director from taking up an appointment) was placed above due regard to the public interest. In fairness, Dr Moyes, like the Trust Board, was faced with a situation which had been commonly dealt with in the health system in a similar way before. He also had to make a balanced judgement about the proper scope of responsibility it was appropriate to leave to the Trust's Board for holding its Chief Executive to account.

Monitor as a separate regulator

10.214 Dr Moyes told the Inquiry that there had been a debate over the years about whether Monitor and the healthcare regulator should be separate. He believed that such a distinction was important because there was always a temptation to solve financial issues by measures which affected the quality of care and separation of function made that more difficult. That remained his view.[197]

10.215 The erroneous authorisation of the Trust as an FT came about almost entirely because the HCC and Monitor were separate organisations, going about their regulatory business without coordinating their activities with each other. This was not just a matter of communication but of different, unaligned methods of assessment. Thus, no effective consideration was given to the potential effects of cost savings and staff cuts on patient safety and quality. The HCC had little by way of financial expertise available to it, and Monitor, likewise, little clinical resource.

10.216 The reluctance of Monitor to act without specific recommendations from the HCC or before its investigation was concluded, and the disconnect between its approach to a serious governance issue to the approach of the HCC, combined to cause an unacceptable delay in regulatory action being taken.

10.217 In January 2013 Monitor published a report on the Trust by its Contingency Planning Team for the Trust.[198] This examined the Trust's operational, clinical and financial sustainability. It concluded that in spite of significant improvements in operational structures it was neither financially not clinically sustainable. This was largely on the grounds that it was struggling to achieve necessary staffing levels and it could not achieve medium term financial sustainability without further significant external financial intervention, and that without further cash support it would be unable to pay its debts and as such was insolvent. It had received £21 million cash support from the DH in the year 2011/12. It was unlikely to be able to continue to meet the cost savings required to break even.

10.218 The Inquiry has not evaluated the sustainability report, which only arrived very shortly before publication of this report, but it is to be noted that it undertook an assessment for Monitor not just of operational and financial issues but of clinical sustainability. It did so by reference to the previous reports on the Trust, and guidance from Royal Colleges and NCEPOD on staffing and activity levels for various services. There was also reference to performance against CQC requirements.

197 Moyes T93.114–115
198 *Mid Staffordshire NHS Foundation Trust – Assessment of Sustainability*, Ernst & Young, McKinsey & Co, January 2013 Monitor. www.monitor-nhsft.gov.uk/node/1953

10.219 Dr Moyes's argument against a union between the two regulators is understandable but does not outweigh the potential advantages. These include:

- The ability to formulate a common strategic approach to the regulation of safety, quality and governance;
- Easier practical recognition of the importance of putting the interests of patient safety and quality of care at the forefront of all activity;
- Alignment of assessment of financial and corporate governance with the needs of patients, and the assessment of the impact of financial measures on patient safety and quality of care;
- Better coordination of regulatory assessment and intervention;
- Swifter decision-making in a unified structure.

10.220 Some of these can be achieved by the better communication and exchange of information, and increased clarification of roles and responsibilities (particularly given the CQC's powers of intervention) that has been undertaken already. However, there appears to remain a separation of the continuing assessment of the compliance of financial and corporate governance, which is Monitor's role, from the assessment of clinical governance and compliance with quality standards, which is the CQC's role. Only joining them together can produce a common approach and accountability. This could be more effectively achieved through a joinder of all aspects of the regulation of the operation of FTs in one regulator. Monitor could then focus on its residual role as a regulator of the health economy. While the recent sustainability report, described above, indicates that Monitor is paying greater attention to clinical sustainability, such assessments could still be more effectively achieved by one regulator being empowered to consider all aspects of a case.

10.221 Were such a joinder to be implemented, it would be very important that it be undertaken incrementally and after thorough planning. Such a move should not be used as a justification for reduction of the resources allocated to this area of regulatory activity. It would be vital to retain the corporate memory of both organisations.

Summary of recommendations

Recommendation 19

There should be a single regulator dealing both with corporate governance, financial competence, viability and compliance with patient safety and quality standards for all trusts.

Recommendation 31

Where aware of concerns that patient safety is at risk, Monitor and all other regulators of healthcare providers must have in place policies which ensure that they constantly review whether the need to protect patients requires use of their own powers of intervention to inform a decision whether or not to intervene, taking account of, but not being bound by, the views or actions of other regulators.

Recommendation 32

Where patient safety is believed on reasonable grounds to be at risk, Monitor and any other regulator should be obliged to take whatever action within their powers is necessary to protect patient safety. Such action should include, where necessary, temporary measures to ensure such protection while any investigation required to make a final determination is undertaken.

Recommendation 33

Insofar as healthcare regulators consider they do not possess any necessary interim powers, the Department of Health should consider introduction of the necessary amendments to legislation to provide such powers.

Recommendation 60

The Secretary of State should consider transferring the functions of regulating governance of healthcare providers and the fitness of persons to be directors, governors or equivalent persons from Monitor to the Care Quality Commission.

Recommendation 61

A merger of system regulatory functions between Monitor and the Care Quality Commission should be undertaken incrementally and after thorough planning. Such a move should not be used as a justification for reduction of the resources allocated to this area of regulatory activity. It would be vital to retain the corporate memory of both organisations.

Recommendation 62

For as long as it retains responsibility for the regulation of foundation trusts, Monitor should incorporate greater patient and public involvement into its own structures, to ensure this focus is always at the forefront of its work.

Recommendation 63

Monitor should publish all side letters and any rating issued to trusts as part of their authorisation or licence.

Recommendation 73

The Department of Health's regular performance reviews of Monitor (and the Care Quality Commission) should include an examination of its relationship with the Department of Health and whether the appropriate degree of clarity of understanding of the scope of their respective responsibilities has been maintained.

Recommendation 74

Monitor and the Care Quality Commission should publish guidance for governors suggesting principles they expect them to follow in recognising their obligation to account to the public, and in particular in arranging for communication with the public served by the foundation trust and to be informed of the public's views about the services offered.

Recommendation 75

The Council of Governors and the board of each foundation trust should together consider how best to enhance the ability of the council to assist in maintaining compliance with its obligations and to represent the public interest. They should produce an agreed published description of the role of the governors and how it is planned that they perform it. Monitor and the Care Quality Commission should review these descriptions and promote what they regard as best practice.

Recommendation 76

Arrangements must be made to ensure that governors are accountable not just to the immediate membership but to the public at large – it is important that regular and constructive contact between governors and the public is maintained.

Recommendation 77

Monitor and the NHS Commissioning Board should review the resources and facilities made available for the training and development of governors to enhance their independence and ability to expose and challenge deficiencies in the quality of the foundation trust's services.

Recommendation 78

The Care Quality Commission and Monitor should consider how best to enable governors to have access to a similar advisory facility in relation to compliance with healthcare standards as will be available for compliance issues in relation to breach of a licence (pursuant to section 39A of the National Health Service Act 2006 as amended), or other ready access to external assistance.

Recommendation 79

There should be a requirement that all directors of all bodies registered by the Care Quality Commission as well as Monitor for foundation trusts are, and remain, fit and proper persons for the role. Such a test should include a requirement to comply with a prescribed code of conduct for directors.

Recommendation 82

Provision should be made for regulatory intervention to require the removal or suspension from office after due process of a person whom the regulator is satisfied is not or is no longer a fit and proper person, regardless of whether the trust is in significant breach of its authorisation or licence.

Recommendation 83

If a "fit and proper person test" is introduced as recommended, Monitor should issue guidance on the principles on which it would exercise its power to require the removal or suspension or disqualification of directors who did not fulfil it, and the procedure it would follow to ensure due process.

Recommendation 84

Where the contract of employment or appointment of an executive or non-executive director is terminated in circumstances in which there are reasonable grounds for believing that he or she is not a fit and proper person to hold such a post, licensed bodies should be obliged by the terms of their licence to report the matter to Monitor, the Care Quality Commission and the NHS Trust Development Authority.

Recommendation 85

Monitor and the Care Quality Commission should produce guidance to NHS and foundation trusts on procedures to be followed in the event of an executive or non-executive director being found to have been guilty of serious failure in the performance of his or her office, and in particular with regard to the need to have regard to the public interest in protection of patients and maintenance of confidence in the NHS and the healthcare system.

Recommendation 86

A requirement should be imposed on foundation trusts to have in place an adequate programme for the training and continued development of directors.

Chapter 11
Regulation: the Care Quality Commission

Key themes

- The Care Quality Commission (CQC) strategy has been constrained by its resources and lacks the time to carry out properly the responsibilities it has been given in statute by the Department of Health (DH).
- There are difficulties in the interpretation and application of the regulatory standards and outcomes overseen by CQC.
- The CQC faces challenges in enforcing the regulatory requirements with regard to staffing through lack of guidance on required staff levels.
- While a breach of the regulations can be a criminal offence, this only arises if a warning notice requiring remedy of a breach has been served and not complied with.
- It would be difficult to determine whether there had been a breach of the regulatory requirements for clinical governance.
- The CQC has focused on registration at the expense of monitoring and inspections.
- The skills base and effectiveness of CQC's inspectors may have been diluted by converting them to general roles, by staff perception of the quality of training and by concerns about changes in the frequency of required inspections.
- The CQC needs to draw on a wider range of information to assess risk (for example, complaints information, coroners' Rule 43 letters, quality accounts, peer review) and the information flows from other organisations need to be preserved and strengthened in the reforms to health structures (for example, patient safety alerts following the abolition of the National Patient Safety Agency), and to continue to develop the Quality Risk Profile.
- The CQC has an unhealthy culture, in which senior managers are more concerned about public image than delivery, which is hostile to internal and external criticism, and in which staff feel under pressure and unsupported.
- The CQC's role should focus on regulating clear fundamental standards that have been developed with input from patients and clinicians.

- The CQC has become more effective as it has focused on themed inspections, but it should consider developing a specialist cadre of hospital inspectors supported by service user representatives, clinicians and other specialists.
- Patient user groups have not to date been embedded in the CQC itself or in its culture and an opportunity has been missed to obtain the patient perspective.

Introduction

11.1 The Inquiry has received extensive evidence about the CQC. It is necessary to describe the limits of the relevance of this evidence.

11.2 The Terms of Reference require the Inquiry to examine the operation of regulators in relation to their monitoring role at the Trust between January 2005 and March 2009, inclusive of the actions of the CQC. The CQC points out, correctly, that it was not in existence as such during that period, and, therefore, it had no role of the nature described in that part of the terms of reference. It is the statutory successor to the Healthcare Commission (HCC) and has continued to assist the Inquiry by affording access to the HCC's archived records and other information, as well as facilitating the appearance of the HCC as a Core Participant.

11.3 However, the Terms of Reference also require the Inquiry to identify the lessons to be learnt and:

> *... in identifying the relevant lessons to have regard to the fact that the commissioning, supervisory and regulatory systems differ significantly from those in place previously and the need to consider the situation both then and now ...*

11.4 Clearly, that requires the Inquiry to inform itself of the nature of the regulatory system as it operates now, as represented by, among others, the CQC, and to form some judgement as to its effectiveness in identifying concerns in provider trusts. This consideration cannot limit itself to purely organisational matters, but extends to the contribution the CQC makes to the cultural climate of the healthcare system, and the extent to which its regulatory approach is likely to detect and act on issues such as those which arose at Stafford at a significantly earlier point in time.

11.5 What the Terms of Reference do not require the Inquiry to do is to review the CQC's general performance. In any event, there have been other recent reports on this topic:

- The House of Commons Health Select Committee reported in September 2011 on its accountability hearing with the CQC;[1]
- A report by the National Audit Office published in December 2011;[2]
- A performance and capability review conducted by the DH which was published in February 2012;[3]
- A report of the Public Accounts Committee in March 2012.[4]
- A report of the House of Commons Health Select Committee published on 9 January 2012.[5]

11.6 These publications have informed the Inquiry of the current context in which the lessons to be learned from the Inquiry are to be applied.

11.7 The CQC has invited the Inquiry, in its submissions, to avoid personal criticism of individuals in the CQC, as the initial procedural statement of the Inquiry stated that such criticisms would only be made where necessary for the purpose of learning lessons.[6] One of the areas identified in that statement for consideration was:

> *The extent to which the relevant organisations, as constituted and operating today, would have identified and acted on the deficiencies at the Trust earlier than in fact was the case ...*[7]

11.8 In order to fulfil that task, it may be necessary to look critically at some of the activities of the CQC about which the Inquiry has heard. This may not require express personal criticism of individuals, but it may be that the implication of such criticism is inevitable.

11.9 This report has focused on the position as disclosed in the evidence presented to it before and during the oral hearings. Where developments since then have been taken into account they are referred to in the text. Generally, however, it has not been possible to evaluate these. Where any criticism of the CQC or its officials is made this relates, unless made clear to the contrary, to the period up to the end of the oral hearings.

1 *Annual Accountability Hearing with the Care Quality Commission: Ninth report of session 2010–12*, HC 1430, Stationery Office (14 September 2011), www.publications.parliament.uk/pa/cm201012/cmselect/cmhealth/1430/1430.pdf. At the time of writing the CQC had again been scrutinised by the Health Select Committee in September 2012.

2 *The Care Quality Commission: Regulating the quality and safety of health and adult social care*, HC 1665, Comptroller and Auditor General, (2 December 2011), www.nao.org.uk/publications/1012/care_quality_commission.aspx

3 *Performance and Capability Review, Care Quality Commission*, Strategy Group, DH (February 2012), www.dh.gov.uk/health/2012/02/cqc-performance-review/

4 *The Care Quality Commission: Regulating the quality and safety of health and adult social care – Seventy-eighth Report of Session 2010-12* (12 March 2012) House of Commons Committee of Public Accounts, www.parliament.uk/business/committees/committees-a-z/commons-select/public-accounts-committee/Publications/previous-sessions/

5 2012 accountability hearing with the Care Quality Commission, 7th Report of Session 2012-13, AC 592

6 CLO000000483, *the Care Quality Commission's closing submissions*, Part 1 – Preliminary Points, page 8, para 14

7 *The Chairman's Procedural statement for the Public Inquiry into the operation of commissioning, supervisory and regulatory bodies for Mid Staffordshire NHS Foundation Trust January 2005–March 2009,* para 4(h), www.midstaffspublicinquiry.com/key-documents

Legislative framework

11.10 The regime which the CQC provides is a very different one to that for which the HCC was responsible. It has two principal functions:

- The registration of providers conducting a "regulated activity" – conducting such activities without being registered is a criminal offence, as is the making of a false declaration in support of an application for registration.
- Reviewing NHS providers and Primary Care Trusts (PCTs) regularly:
 - Using indicators approved by the Secretary of State in accordance with a method statement that must also be approved by the Secretary of State;
 - By "special" reviews or investigations, obligatorily if the Secretary of State requests, otherwise at the CQC's discretion;
 - Similarly, "periodic reviews" of regulated activities may be required by the Secretary of State or otherwise at the CQC's discretion.

11.11 The statutory objectives of the CQC in carrying out these functions were initially stated as follows:

> *(1) The main objective of the Commission in performing its functions is to protect and promote the health, safety and welfare of people who use health and social care services.*
>
> *(2) The Commission is to perform its functions for the general purpose of encouraging—*
>
> *(a) the improvement of health and social care services,*
>
> *(b) the provision of health and social care services in a way that focuses on the needs and experiences of people who use those services, and*
>
> *(c) the efficient and effective use of resources in the provision of health and social care services.*[8]

11.12 The CQC is required to have regard to a number of matters in carrying out its duties, including:

- Views expressed by or on behalf of members of the public and by Local Involvement Networks (LINks) about health and social care services;
- Experiences of people who use health and social care services and their families and friends;
- The need to protect and promote the rights of service users, in particular, vulnerable adults and children;
- The need for proportionality in regulation;

8 Health and Social Care Act 2008, section 3, www.legislation.gov.uk/ukpga/2008/14/contents

- Developments in regulatory action;
- Best practice among persons performing functions comparable to those of the CQC (including the principles under which regulatory action should be transparent, accountable and consistent);
- Such aspects of Government policy as the Secretary of State may direct.[9]

11.13 The powers of the CQC include:

- Cancellation of registration on grounds that include non-compliance with statutory requirements;
- Issue of a warning notice to a registered person (including an organisation) requiring compliance with statutory requirements – any such failure cannot be relied upon as a ground for cancellation, suspension, or variation of a condition of registration if remedied in accordance with the warning notice. Some CQC witnesses complained that this meant that a pattern of serial but corrected non-compliance could not be relied on as ground for cancellation;
- Making urgent applications to a magistrate for cancellation, suspension or variation of registration where it appeared there would be a serious risk to life, health or well-being if the order were not made;
- It also has power to prosecute offenders in respect of a number of criminal offences created by the Health and Social Care Act 2008:[10]
 - Breach of a condition of registration;
 - Breach of a regulation specifying that a breach is an offence;
 - Making knowingly materially false or misleading statements in an application for registration.

However, its powers to prosecute for a breach of the regulations setting standards of service are limited to cases where a warning notice requiring remedial action has been served and not complied with. Even then it is a defence for the registered person to prove that they took all reasonable steps and exercised all reasonable diligence to ensure compliance.[11]

Initial challenges

Inheriting three different systems and structures

11.14 The CQC was created out of an amalgamation of the HCC, the Mental Health Act Commission (MHAC) and the Commission of Social Care Inspection (CSCI).[12] Each of these organisations had different duties, areas of activity and expertise. Unsurprisingly, each had a different approach to the performance of its duties.

9 Health and Social Care Act 2008, section 4, www.legislation.gov.uk/ukpga/2008/14/contents
10 Health and Social Care Act 2008, sections 33 to 37
11 Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 [SI 2010/781] Reg 27
12 CQC00000000001, CQC Provisional statement, para 3

11.15 The HCC had the general function of encouraging improvement in the provision of healthcare by and for National Health Service bodies. In particular, it was concerned with the availability of and access to healthcare, the quality and effectiveness of healthcare, the economy and effectiveness of this healthcare, and the availability and quality of information provided to the public about that healthcare. In addition, it had a duty to review formal complaints and investigate serious failures in relation to public, private and voluntary sector healthcare service providers (see *Chapter 9: Regulation: the Healthcare Commission*).[13]

11.16 MHAC was established by the Mental Health Act 1983 (the 1983 Act) as a monitoring body whose primary concern was the legality of detention and the protection of the human rights of individuals detained under the 1983 Act. Its remit included reviewing the operation of the 1983 Act in respect of patients detained or liable to be detained under it, investigating complaints where these fell within the MHAC's remit and appointing medical practitioners to give second opinions in cases where this is required under the 1983 Act. The MHAC was also to provide to Parliament a report every two years, monitor the implementation of a Code of Practice and propose amendments to Ministers.[14]

11.17 The CSCI was established under the Health and Social Care Act 2003 as an inspectorate for adult social care in England. It was concerned with the management of the services and the efficiency of their provision. It was responsible for the provision of inspection reports relating to the quality and quantity of social care services at both local and national levels, the investigation of complaints and the enforcement of actions when services did not meet minimum standards.[15]

11.18 In bringing together these three organisations, the CQC decided it was necessary to merge functions across healthcare, mental healthcare and social care, so that these were carried out by a unified staff.

11.19 The CQC perceived weakness in the approaches of each but also elements of merit which it wished to adopt and develop.

11.20 The CQC was placed under considerable time pressure to undertake the merger of the three organisations, all with different responsibilities, staff and methodologies, into a brand new registration system that was the subject of regulations, which, in some cases, only became available a matter of weeks before the CQC went 'live.'[16]

13 Health and Social Care (Community Health and Standards) Act 2003, section 41, Chapter 3 and Schedule 6, www.legislation.gov.uk/ukpga/2003/43/contents
14 Mental Health Act 1983, section 121, www.legislation.gov.uk/ukpga/1983/20/contents
15 Health and Social Care (Community Health and Standards) Act 2003, section 42, Chapter 5 and Schedule 7, www.legislation.gov.uk/ukpga/2003/43/contents
16 Dame Jo Williams T84.97

The scope of the CQC's duties

11.21 The CQC is responsible for regulating providers of:

- adult social care services (such as care homes, nursing homes, and home care agencies);
- NHS services (including hospitals, NHS trusts and foundation trusts, ambulance services and community services);
- Independent healthcare services (including hospitals, clinics and private ambulance services);
- Dental services;
- Independent out of hours medical services.[17]

11.22 There are over 21,000 providers in these categories, spread over more than 36,000 locations in England.

11.23 The CQC is also due to begin regulation of 8,000 providers of primary medical services by April 2013 (delayed from April 2012). There will then be some 45,000 health services for which the CQC will be the regulator.[18]

11.24 The CQC's functions include the registration of service providers; inspection and monitoring of compliance; enforcement; publication of information about health and social care; and additional powers and responsibilities in relation to the protection of rights and interests of patients detained under the Mental Health Act 1983 (section 120).[19]

11.25 The CQC runs a national helpline which, in 2010/11, saw a 13% increase in calls, to a total of 345,000 for the year, including 4,799 'safeguarding' calls. According to the DH's Capability and Performance Review of the CQC:

> *In an average month, the National Customer Service Centre in Newcastle receives 16,350 calls, 4,700 email enquiries and 3,400 electronic applications. These figures include around 284 whistleblowing contacts, 1,990 safeguarding contacts and 19,232 notifications per month. The number of whistleblowing contacts more than tripled from 279 in the first quarter of 2011/12 to 1,161 in the third quarter, although the number of substantive follow-ups has remained relatively stable.*[20]

11.26 In addition to the issues raised by the sheer number of organisations to be regulated, which are continually expanding, the CQC has faced a degree of uncertainty about where and how it

17 *Annual Report and Accounts 2011–12* (12 July 2012), The Care Quality Commission, p52
18 CLO000002333, *Counsel to the Inquiry's closing submissions,* Chapter 16 – Care Quality Commission, paras 13–15
19 *Annual Report and Accounts 2011–12* (12 July 2012), The Care Quality Commission, page 53
20 *The Department of Health's Performance and Capability of the Care Quality Commission* (February 2012), Chapter 2, para 2.11, www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_132791.pdf

should focus its activities. As indicated above, it has a statutory objective of encouraging the improvement of services. However, with the agreement of the DH it has, in fact, sought to focus on compliance with standards. The DH said in the Capability and Performance Review:

> *... there has been some uncertainty over how it fulfils this role with CQC focusing on compliance against essential standards, rather than continuing legacy organisations' role to drive quality improvement above essential standards. This decision was supported by the Department and part of the criticism stems from unpopularity of the decisions, as well as the how the changes in role have been communicated* [sic].[21]

11.27 Cynthia Bower interpreted the duty to encourage improvement narrowly:

> *The 2008 Act requires the CQC to determine whether an organisation is compliant with the essential standards of quality and safety and if not to use its enforcement to make those organisations compliant. By making those organisations compliant we bring about inherent improvement of the standard of care, particularly as the essential standards themselves are outcome based.*[22]

11.28 Dame Jo Williams gave evidence to a similar effect:

> *The SHA role is to assist improvement. CQC does not have a broader improvement role. Our function is to look at and take a view as to whether the 16 essential standards are being met.*[23]

Resources

11.29 The financial resources allocated to the new organisation were less than the combined budget of its predecessors, and yet it had a broader remit and a new regulatory regime to put together and run. The previous total budget allocation for the three organisations had been £210 million in 2006/07, whereas the allocated operating cost for the CQC was £165 million.[24] Expenditure was reduced to £139 million in 2010/11 (out of a budget of £164 million). Of this sum, a considerable proportion was devoted to the re-registration of adult social care and independent healthcare providers, as well as registration for the first time of 9,000 dental care workers and independent ambulance providers. As of 2012, the budget is, again, at around £160 million.[25]

21 *The Department of Health's Performance and Capability of the Care Quality Commission* (February 2012), Chapter 2,. para 2.16, www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_132791.pdf
22 Bower WS(2) WS0000037389–90, para 77
23 Dame Jo Williams WS0000032081, para 49.12
24 Bower WS(2) WS0000037363, para 4
25 *The Department of Health's Performance and Capability of the Care Quality Commission* (February 2012), Chapter 2, para 2.5, www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_132791.pdf

11.30 This reduction in resources did not pass without protest. Baroness Barbara Young raised the issue in September 2008 before the CQC formally started work. She expressed concern to the transition team that limited resources might compromise the transition programme.[26]

11.31 She did not consider that matters had improved by the time she left the organisation in December 2009, as she believed that:

> *... resources and staff when I left the CQC were close to becoming insufficient to ensure an effective regulatory regime. My experience in other regulatory fields is that even regular review of quality and risk information needs to be grounded in adequate levels of inspection on the ground by trained inspectors of sufficient seniority and experience. Further staff reductions would have made this difficult.*[27]

11.32 The CQC continued to perceive that it was short of resources. In September 2010, Dame Jo Williams, the CQC Chair at the time, told the House of Commons Select Committee at the annual accountability hearing that it was "struggling to stretch its resources".[28] In June 2011, she told the Committee that the CQC had asked for an additional 10% to allow recruitment of more inspectors. In its 2012 report, the Committee expressed its disbelief that additional resources would solve the CQC's problems, unless it developed a clear strategy.[29] This echoed a finding of the National Audit Office in its December 2011 report that the CQC had underspent its budget for the two previous years (2009/10 and 2010/11) largely due to not filling staff vacancies.[30]

11.33 The evidence before the Inquiry suggested that there was a shortage of staff that was on the way to being corrected by the close of the oral hearings:

- In December 2009, the CQC had 1,960 full-time staff of whom 728 were inspectors with 8 vacancies.
- By June 2011, there were 1,931 full-time staff posts of which 297 were vacant. There were 855 compliance inspector posts of which 133 were vacant. In other words, there were 722 inspectors in post as compared with 720 in December 2009.
- By November 2011, the inspector vacancies had been reduced to 25 and these were all due to be filled by March 2012. Funding had been approved by the DH to increase the

26 BY/3 WS0000053645
27 Young WS0000053612, paras 28–29
28 *Annual Accountability Hearing with the Care Quality Commission: Ninth Report of Session 2010–12*, HC 1430, Stationery Office (14 September 2011), Chapter 2 – The balance between registration and compliance activity, para 27, www.publications.parliament.uk/pa/cm201012/cmselect/cmhealth/1430/1430.pdf
29 *Annual Accountability Hearing with the Care Quality Commission: Ninth Report of Session 2010–12*, HC 1430, Stationery Office (14 September 2011), Chapter 2 – The balance between registration and compliance activity, para 28, www.publications.parliament.uk/pa/cm201012/cmselect/cmhealth/1430/1430.pdf
30 *The Care Quality Commission: Regulating the quality and safety of health and adult social care*, HC 1665 Comptroller and Auditor General (2 December 2011), internal page 8, para 12, www.nao.org.uk/publications/1012/care_quality_commission.aspx

number of inspectors to 955. However, the funding was to be generated by the CQC through efficiency savings.[31]

Independence

11.34 The CQC is a non-departmental public body funded by the DH but accountable directly to Parliament. Its independence of action is potentially circumscribed by its relationship with the Secretary of State for Health:

- Its Commissioners, including the Chair, are appointed, and may be removed, by the Secretary of State.[32]
- The standards required to enforce such appointments to, or removals from, the CQC are laid down by statutory instrument or as directed by the Secretary of State.[33]
- The Secretary of State may direct the CQC to undertake an investigation, a power which has been exercised frequently.
- It must have regard to such aspects of policy as the Secretary of State may direct;
- The DH undertakes performance and capability reviews. The first review, completed after the close of this Inquiry's oral hearings, has been critical of the running of the CQC.[34]

11.35 In the course of the CQC's short life, the influence of the DH has resulted in a focus on 16 out of 28 of the outcomes derived from the regulations.

11.36 Very recently, a request by the then Chair, Dame Jo Williams, that the Secretary of State remove a Commissioner from the Board was rejected (see below).

11.37 The closeness of the relationship between the CQC and the DH appears to have been behind the decision of Baroness Young to resign as Chair in December 2009. She told the Inquiry:

31 CLO00000000475, *CQC closing submissions*, para 315
32 Health and Social Care Act 2008, Schedule 1, para 3
33 Health and Social Care Act 2008, Schedule 1, paras 4–5
34 *The Department of Health's Performance and Capability of the Care Quality Commission* (February 2012), www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_132791.pdf

I resigned for a number of reasons. I actually was looking back on my records yesterday, and at the beginning of September I wrote myself a note saying "Get another job". And I think the reason for that was several fold. One was it was clear to me that the model of an independent regulator, regulating services provided by a Government Minister, was never going to be a satisfactory model. It was always going to be incredibly fraught, because inevitably both the Department and Ministers were torn between wanting good, strong independent regulation of healthcare and knowing that if good, strong independent regulation of healthcare happened, from time to time they would be put in the dock and found wanting. And I think that tension worried me not a little. I felt quite able to resist it, but I could see that in resisting it there would be constant conflict and that didn't feel good.[35]

11.38 She gave a second reason relating to what she foresaw as the effect of a restriction on resources:

But the second reason also was a weight in the scales, and that was I really believed strongly that we could only do a good job if we were on the ground locally inspecting with rigour and understanding what was happening locally in healthcare systems and in hospitals that were delivering services. And I knew that we were finding it quite difficult to ensure that that was the case with the resource we had. And I could see further restrictions in resources on the horizon, because by then it was clear that the service was going to share in cuts. And I could also see that that was going to happen at a time when the quality of care was going to be even more at risk than usual as a result of healthcare cuts in services.

So you'd be a regulator in a very difficult position, with Government, accountable to Government, but responsible really to the public, with less resource to regulate effectively, and services being more at risk. And it just felt to me that that was not a job that my skills were best suited for.[36]

11.39 A third reason was her personal relationship with the DH:

... to be honest, the whole thing was getting so fraught, in terms of the role of the regulator and how we were regarded, and having now been a regulator in three different departments, three different Government departments, responsible for three different Government departments, the relationship with the health department was by far the worst by an order of magnitude. And I didn't see any way that it was going to resolve itself. So despite the fact I'm not a quitter, I quit.[37]

35 Baroness B. Young T110.124
36 Baroness B. Young T110.124–5
37 Baroness B. Young T110.126

... But it was intrinsically because of the way it was set up, reporting to a Government Minister, regulating services that the Government Minister had responsibility for, it seemed to me that that intrinsic conflict was always going to be there, and that meant that you probably needed somebody who was much more flexible than me to head up the process. I wasn't sufficiently flexible and smart to do that.[38]

11.40 Sir Hugh Taylor, DH Permanent Secretary at the time, did not accept this was an accurate reflection of the relationship between the CQC and the DH, but rather a reflection of Baroness Young's perception.[39] He went on to say that tensions were inevitable and were part of the job that had to be managed:

I think if you're going to take on a role as a regulator in an arena as sensitive and politically charged as health, you have to accept that this tension is there. It's just a fact of life. I don't think that Ministers behaved inappropriately in relation to their dealings with Baroness Young, and I don't accept that it's impossible for the Department and Ministers to manage a relationship with the regulator – with a regulator, regulatory body in the health field, which isn't both constructive and in the end to the benefit of patients and the public.

As I say in my own statement, there are moments when this gets very difficult but, to be honest, as I say in my statement, when a body like the Healthcare Commission presents Ministers with a report of the kind that they did in Mid Staffs, it becomes a matter of huge political and public interest, and one has to accept that, and that then gets played out in quite a highly charged atmosphere. It goes with the turf.[40]

Care Quality Commission standards

11.41 The CQC is required to police standards laid down by the DH. Regulations have set out requirements for all providers of care, whether in the NHS or in the private sector. A breach of the requirements of the regulations may be a criminal offence if they so provide. The standards which are set out in a combination of the Health and Social Care Act 2008 and regulations made under the Act, are supplemented by voluminous guidance.[41]

11.42 Essentially, there are 28 outcomes corresponding to the statutory requirements. Of these, 16 are described as key outcomes most directly related to quality and safety, divided among five categories:

38 Baroness B. Young T110.154–6
39 Sir H. Taylor T126.44–45
40 Sir H. Taylor T126.45
41 Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 [SI 2010/781], www.legislation.gov.uk/uksi/2010/781/pdfs/uksi_20100781_en.pdf

Involvement and information:

- Respecting and involving people who use services (outcome 1);
- Consent to care and treatment (outcome 2).

Personalised care, treatment and support:

- Care and welfare of people who use services (outcome 4);
- Meeting nutritional needs (outcome 5);
- Cooperating with other providers (outcome 6).

Safeguarding and safety:

- Safeguarding people who use services from abuse (outcome 7);
- Cleanliness and infection control (outcome 8);
- Management of medicines (outcome 9);
- Safety and suitability of premises (outcome 10);
- Safety, availability and suitability of equipment (outcome 11).

Suitability of staffing:

- Requirements relating to workers (outcome 12);
- Staffing (outcome 13);
- Supporting workers (outcome 14).

Quality and management:

- Assessing and monitoring the quality of service provision (outcome 16);
- Complaints (outcome 17);
- Records (outcome 21).

11.43 There is a sixth category, "Suitability of management", none of the outcomes in which are considered to be "core".

11.44 The outcomes are categorised in a different order than the requirements in the regulations, but the relationship between the two is made clear in the CQC guidance, Guidance About Compliance: *Essential standards of quality and safety,* published initially in March 2010 and now updated in December 2011.[42] This includes guidance on all 28 outcomes although the focus is on the 16 core requirements. The guidance seeks to focus on outcomes, in the sense of what the person receiving care will experience, rather than the input that brings about that result. It is not necessary to analyse each aspect of the regulatory requirements or the outcomes, but a few examples will be considered.

42 CQC00110000050, *Guidance About Compliance: essential standards of quality and Safety* (March 2010), Care Quality Commission, www.cqc.org.uk/sites/default/files/media/documents/gac_-_dec_2011_update.pdf

Safety

11.45 Regulation 9 requires providers to:

> *... take proper steps to ensure that each service user is protected against the risks of receiving care or treatment that is inappropriate or unsafe, by means of—*
>
> *(a) the carrying out of an assessment of the needs of the service user; and*
>
> *(b) the planning and delivery of care and, where appropriate, treatment in such a way as to —*
>
> *(i) meet the service user's individual needs,*
>
> *(ii) ensure the welfare and safety of the service user,*
>
> *(iii) reflect, where appropriate, published research evidence and guidance issued by the appropriate professional and expert bodies as to good practice in relation to such care and treatment, and*
>
> *(iv) avoid unlawful discrimination including, where applicable, by providing for the making of reasonable adjustments in service provision to meet the service user's individual needs.*[43]

11.46 This requires a provider to "take proper steps to ensure" that a patient is "protected against the risks" of "inappropriate or unsafe" treatment. The protection is to be achieved by various specified means including the provision for each patient of a needs assessment, a care plan and delivery of the planned care to the patient. The care and treatment has to meet the patient's needs and ensure his or her welfare and safety, and reflect current guidance and good practice.

11.47 Bearing in mind that breach of the regulation is a criminal offence, there are uncertainties with regard to the extent of its requirements:

- The regulation does not itself define what is meant by "proper steps". As far as the researches by the Inquiry have been able to establish, there has been no judicial determination of the meaning of this term in this context. There are a number of possible meanings, including: steps honestly believed by the provider to be sufficient; those steps any competent provider would take; all practicable steps; or all reasonably practicable steps.
- The meaning of "ensuring" that patients are protected from risk may depend on the meaning established for the term "proper steps". The requirement could, depending on its construction, mean no more than that the provider must put in place a system which they

43 CQC00110000113, *Guidance About Compliance: Essential standards of quality and safety* (March 2010), Care Quality Commission, page 62

reasonably expect would protect patients from the risks referred to. This is not, of course, the same thing as guaranteeing that a patient does not receive unsafe treatment.
- Still less is it likely that the requirement means that every patient will in fact receive a needs assessment or a care plan.

11.48 Therefore, the regulation requires the provider to have a system intended to achieve an outcome for the patient, rather than either prescribing what the system for achieving it might be, or making it an offence for the outcome not to be in fact provided for every patient.

11.49 The guidance addresses this regulation in outcome 4. Although the outcome's title ("care and welfare of people who use services") does not mention safety, the requirement for the provision of safe care is recognised in the text in its expectation of what the patient will experience:

> *... effective, safe and appropriate care, treatment and support that meets their needs and protects their rights.*[44]

11.50 This does not mean there is a certainty of such a provision, as demonstrated by the expressed expectation that a provider will "reduce the risk" of receiving unsafe or inappropriate care, treatment and support by the steps set out in the regulation.[45] There follows a list of prompts around matters care planning should seek to achieve. With systems for learning from mistakes, incidents and complaints and so on, the list of "prompts" is wide ranging. It includes an expectation that, where appropriate, patients will know the names of those who treat them, as well as an expectation that staff will detect quickly a deterioration in the patient's condition and respond immediately. It might be thought that the first of these is important to a patient's welfare and involvement, while the latter is essential for the patient's safety. However, such a wide-ranging list is perhaps inevitable because the regulation puts together a requirement in relation to welfare and safety.

Staffing

11.51 Regulation 22 provides:

> *In order to safeguard the health, safety and welfare of service users, the registered person must take appropriate steps to ensure that, at all times, there are sufficient numbers of suitably qualified, skilled and experienced persons employed for the purposes of carrying on the regulated activity.*[46]

44 CQC00110000114, *Guidance About Compliance: Essential standards of quality and safety* (March 2010), Care Quality Commission, page 63
45 CQC00110000114, *Guidance About Compliance: Essential standards of quality and safety* (March 2010), Care Quality Commission, page 63
46 Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 [SI 2010/781], Reg 22, www.legislation.gov.uk/uksi/2010/781/pdfs/uksi_20100781_en.pdf

11.52 As with the previous regulatory requirements considered, it is an offence not to comply with regulation 22. The same issues arise with regard to the precise ambit of this regulation, except here the actions required are described as "appropriate" rather than "proper" steps. In tone the regulation might suggest that this a direct requirement to have sufficient staff on duty, but there is no measure suggested for what is to be deemed "sufficient". The implication may be that the numbers should be those that any reasonably competent manager would ensure were available, but this is not made explicit.

11.53 Outcome 13, which addresses this regulation, does suggest that the regulation requires the actual provision of sufficient staff, as opposed merely to a system designed to bring that about.

> *People who use services:*
>
> - *Are safe and their health and welfare needs are met by sufficient numbers of appropriate staff.*
>
> *This is because providers who comply with the regulations will:*
>
> - *Make sure that there are sufficient staff with the right knowledge, experience, qualifications and skills to support people.*[47]

11.54 The "prompts" given to managers in relation to this outcome offer the same impression. They include the suggestion that they:

> - *Can demonstrate that there are sufficient numbers of staff with the right competencies, knowledge, qualifications, skills and experience to meet the needs of people who use services at all times.*
> - *Can show that as far as possible that there are enough staff who know the needs of people using the service, meaning that people who use services can expect a consistency of care.*
> - [Are] *able to demonstrate that they have carried out a needs analysis and risk assessment as the basis for deciding sufficient staffing levels.*
> - *Ha*[ve] *management structures, systems and clear human resources procedures followed in practice, monitored and reviewed that enable the effective maintenance of staffing levels.*
> - *Can respond to unexpected changing circumstances in the service, for example to cover sickness, vacancies, absences and emergencies.*
> - *Can respond to expected changing circumstances in the service, with particular regard to planned service developments, workforce changes, staff training, planned absences and changes in legislation.*

47 CQC00110000183, *Guidance About Compliance: Essential standards of quality and safety* (March 2010), Care Quality Commission, page 132

- *Takes into account relevant guidance, including that from the Care Quality Commission's Schedule of Applicable Publications …*[48]

11.55 The publications referred to are generic and do not include any guidance to skills, staffing levels and skill mix from professional regulatory and representative bodies, such as the DH and the National Institute for Health and Clinical Excellence (NICE).

11.56 The Inquiry was told that the CQC does not "interfere" with staffing levels, although Dame Jo Williams provided a caveat to this:

> *… exceptions are made where there is serious concern … If we think that staffing levels are causing real risk to patient care then I think the CQC should step in, but otherwise we shouldn't be prescriptive.*[49]

11.57 In fact, the CQC did "step in" at the Trust in relation to staffing. In its application for registration in January 2010, it declared itself compliant with outcome 13, although non-compliant with five other outcomes. On reviewing the Trust, the CQC found that there was still a nurse staffing deficit of 11% and 130 nursing staff were not in post. While this discovery did not prevent the CQC grading the application for registration, conditions were imposed. A formal notice was issued on 12 March 2010, which included a compliance condition in relation to staffing, requiring that sufficient staff be in place by 1 April 2010;[50] compliance was confirmed at subsequent reviews.

11.58 Amanda Sherlock, Director of Operations Delivery at the CQC, pointed out to the Inquiry that there are few, if any, national guidelines as to staff levels required, an exception being maternity.[51] Therefore, the CQC looks at the outcomes for patients to determine whether the staff are sufficient. Vacancy and agency rates are taken into account in deciding whether to undertake a review. She considered that specifying minimum numbers of staff was too difficult.[52] Where there are concerns about the standard of care, the CQC will look at staffing rotas. Where they consider that the staff may not be sufficient, advice will be sought from a relevant Royal College.[53]

11.59 Cynthia Bower, then CQC Chief Executive, drew a distinction between prescribing staffing levels and examining on the spot whether there were sufficient nurses:

48 CQC00110000184, *Guidance About Compliance: Essential standards of quality and safety* (March 2010), Care Quality Commission, page 133
49 Dame Jo Williams WS0000032079, paras 49.8–9,
50 Sherlock WS000032387–9, paras 316–322,, Sherlock WS0000032294–6, paras 45–48
51 Sherlock WS0000032352, para 204
52 Sherlock T85.137–138
53 Sherlock T85.140–141

So we will look at staffing when we go in ... whether it's in a care home, whether it's a domiciliary care provider, whether it's in an elderly care ward in – an acute hospital, we will talk to staff and talk to patients about sufficient numbers of staffing being available to ensure that they are appropriately cared for, that their needs are met, that if they have concerns that they are addressed. But that's different from saying that CQC will itself prescribe what an appropriate level of staffing would be.[54]

11.60 However, she did accept it would be helpful to the CQC's work for there to be more guidance available, particularly if it came from the Royal Colleges.[55]

11.61 Another voice arguing against prescriptions of staffing levels was Dr William Moyes, the former Executive Chairman of Monitor, who thought it would be wrong for commissioners to lay down requirements.[56]

11.62 Sir David Nicholson, the Chief Executive of the NHS, told the Inquiry that the issue of staffing levels was long standing:

... it's been an issue since I started in the NHS, to be frank, and it's an issue across the world. This discussion and controversy goes on in most healthcare systems, and most healthcare systems do not have a single set of directions that set out by ward what minimum standards are ... because it is so difficult.[57]

11.63 He said that, every time a requirement had been tried in other countries, it had not been effective because of the difficulty of getting the level right.

11.64 Some guidance on nurse to patient ratios is offered by the Royal College of Nursing (RCN). Dr Peter Carter, Chief Executive and General Secretary of the RCN, explained that understaffed wards are likely to suffer from higher mortality rates. However, he also said that the calculation of such ratios are factually sensitive. A higher number of individual rooms, patients requiring more care or elderly patients suffering from Alzheimer's will indicate the need for a higher ratio. Efficient management can also reduce the required ratio. Generally, a ratio of 65% qualified to 35% unqualified staff should be on duty at the same time. However, again this is sensitive to the architecture of a ward and the individuals' levels of training, competency and skill.[58]

54 Bower T87.67
55 Bower T87.67–9
56 Moyes T93.172–173
57 Nicholson T128.45
58 P Carter WS0000003369, para 86; T52.79–81

11.65 The Inquiry also heard that a national data set is available, whereby the staffing levels at different providers can be compared.[59]

The overall limitation on the enforcement of the regulations

11.66 While a breach of the regulations considered above is a criminal offence, the CQC may not prosecute a provider for such a breach unless a warning notice requiring action to secure compliance has been served, and the provider has not secured compliance within the required time.[60] This means that however egregious the offence, no prosecution can be brought without a warning notice procedure. For example, if on the facts of the Mrs Gillian Astbury case, described elsewhere in this report, it was considered there had been one or more breaches of regulation 9, no prosecution could be brought because there had been no prior warning notice.

Clinical governance

11.67 The regulations and the outcomes derived from them do not prescribe a system of clinical governance but rather have within them the elements of good governance. As the CQC guide puts it:

> *We have not specifically described what a system of clinical governance should look like in this guide, as clinical governance has several purposes beyond simply establishing the essential standards of quality and safety. However, it is important for providers of healthcare to have a strong system of clinical governance in place. While the guide as a whole supports the development of an effective clinical governance system, we believe that the outcomes and prompts for the following outcomes are of particular importance.*[61]

11.68 It goes on to refer to outcomes 1, 2, 4, 6 to 12, 14, 16, 17, and 21.

11.69 Regulation 10 provides that:

> *The registered person must protect service users, and others who may be at risk, against the risks of inappropriate or unsafe care and treatment, by means of the effective operation of systems designed to enable the registered person to—*
>
> - *regularly assess and monitor the quality of the services provided in the carrying on of the regulated activity against the requirements set out in this Part of these Regulations; and*

59 Straughan T99.169
60 Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 [SI2010/781], Reg 27, www.cqc.org.uk/sites/default/files/media/documents/20120321_final_judgement_framework_for_publication.pdf
61 CQC00110000088, *Guidance About Compliance: Essential standards of quality and safety* (March 2010), Care Quality Commission, p37

- *identify, assess and manage risks relating to the health, welfare and safety of service users and others who may be at risk from the carrying on of the regulated activity.*[62]

11.70 The core obligation of this regulation is the "effective operation of systems" for the purpose of protecting patients from the risk of inappropriate or unsafe treatment. These systems must be "designed" to assess and monitor the quality of services, and "to identify, assess and manage" the health, welfare and safety of service users.

11.71 For the purpose of carrying out this core obligation the provider must do a number of things, including:

- Obtaining, where "appropriate", professional advice;
- Having "regard to" service users' complaints and comments, investigations, appropriate advice, and CQC reports and reviews;
- Making changes to the treatment and care provided to "reflect information" of "which it is reasonable to expect that a registered person should be aware" relating to incident analysis, service reviews, clinical audits and research projects;
- Establishing mechanisms for ensuring that treatment decisions are taken by an appropriate person who is answerable to a person responsible for supervising him or her;
- Regularly seeking the views of service users on their experience of care and treatment.

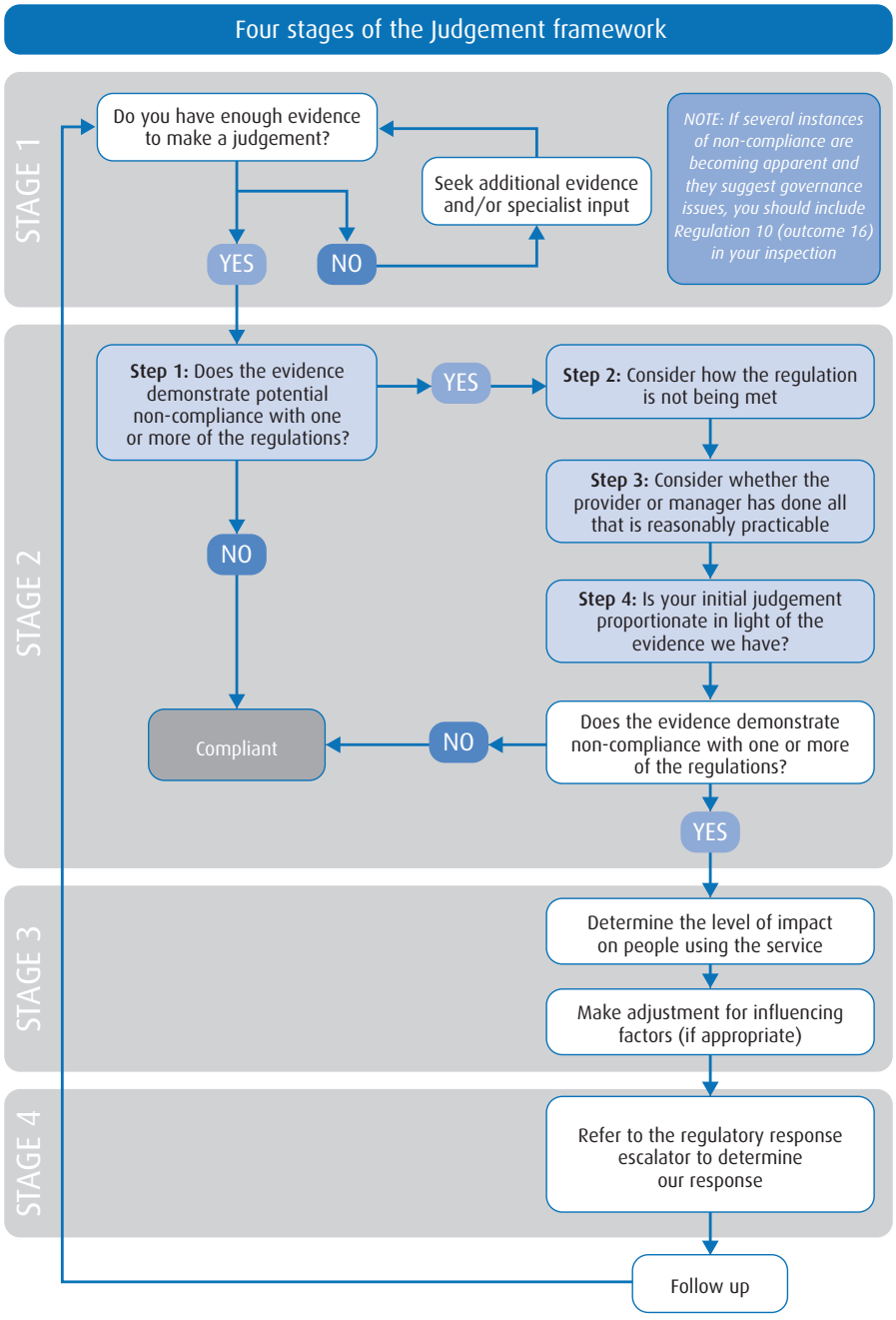
11.72 The regulation covers a multiplicity of activities required for clinical governance. It does not of itself set a standard to be reached, but includes terms, some of which are quoted directly above, importing concepts of judgement, reasonableness and the need to take account of certain types of information. Given the complexity of the text of the regulation, it would be difficult for a registered person to determine whether a particular course of action was or was not compliant with the regulation. It is therefore understandable that a prosecution can only be brought for a breach of it after a warning and a chance to remedy the breach have been given.

Scrutiny of compliance

11.73 The CQC has set out in its *Judgement Framework* its approach to deciding whether or not an organisation is in compliance with the required outcomes.[63] This sets out the methodology in a helpful diagram.[64]

62 Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 [SI 2010/781], Reg 10, www.legislation.gov.uk/ukdsi/2010/781/pdfs/ukdsi_9780111491942_en.pdf
63 *Judgement Framework*, CQC (April 2012), www.cqc.org.uk/sites/default/files/media/documents/20120321_final_judgement_framework_for_publication.pdf
64 *Judgement Framework*, CQC (April 2012), page 5, www.cqc.org.uk/sites/default/files/media/documents/20120321_final_judgement_framework_for_publication.pdf

Figure 11.1: The Care Quality Commission's Judgement framework



11.74 Stage 1 of an assessment is to determine whether sufficient evidence has been collected to make a judgement on compliance. This takes into account, among other factors, relevance, currency, reliability, usability, and sufficiency. Additionally, inspectors will consider whether the evidence demonstrates the processes and governance the provider or manager has in place, and whether specialist input is needed to analyse it:

This includes written advice, guidance and briefings that can be accessed anytime, as well as input from individuals or groups where it is deemed appropriate.[65]

11.75 The second stage is to consider whether the evidence demonstrates non-compliance. There are four steps in this stage.

11.76 Under the regulations, it is a defence in a prosecution for an offence of non-compliance for:

... the registered person to prove that they took all reasonable steps or exercised all due diligence to ensure that the provision in question was complied with.[66]

11.77 Therefore, the third of the second-stage steps is to judge whether the organisation has done all that is reasonably practicable to ensure compliance. The judgement framework observes:

Evidence of a lack of effort, time or money will not, in itself, be accepted as a rationale for a provider or manager failing to achieve and maintain compliance with regulations. However, where complete control of a risk would require a disproportionate and unjustifiable expenditure or resource, partial mitigation of the risk may be acceptable.[67]

11.78 The fourth step is to judge whether a finding of non-compliance is proportionate in light of the evidence. One inadequately managed complaint may not amount to non-compliance in an otherwise well-run system:

For example, during an inspection we may find an isolated example of one badly-handled complaint but, overall, the evidence indicates an effective complaints system where people are supported to make complaints, and complaints are handled and responded to effectively. In this instance (and depending on the outcome of the badly-handled complaint), it would not be proportionate for us to judge the provider as non-compliant with Regulation 19 (Outcome 17) based on this specific evidence.

11.79 Where non-compliance is found, an assessment is made as to whether its impact on service users is minor, moderate or major (Stage 4). If multiple non-compliance is found, an assessment will usually be made of outcome 16 (assessing and monitoring the quality of service provision) as compliance by the organisation with this requirement would be expected to have detected and addressed multiple non-compliance.

65 *Judgement Framework*, CQC (April 2012), page 8, www.cqc.org.uk/sites/default/files/media/documents/20120321_final_judgement_framework_for_publication.pdf
66 Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 [SI 2010/781], Reg 27(4), www.legislation.gov.uk/ukdsi/2010/781/pdfs/ukdsi_9780111491942_en.pdf
67 *Judgement Framework*, CQC (April 2012), page 11, www.cqc.org.uk/sites/default/files/media/documents/20120321_final_judgement_framework_for_publication.pdf

11.80 Having determined that there is non-compliance, the CQC moves on to determine its regulatory response. A table from the CQC guidance showing the options is set out below:

Table 11.1: The Care Quality Commission's guidance on responses to non-compliance

Regulatory response	Outcome from the action
Formal regulatory action:	
Compliance action	• Provider and/or manager submits a robust report detailing the actions they intend to take to become compliant within the timeframe that they have agreed with us. • An update is required from the provider and/or manager on progress and upon completion of actions to become compliant. Follow-up is either through a desktop review or an inspection.
Enforcement action:	
Warning notice	• Provider and/or manager implements the necessary changes to become compliant within the timeframe imposed. • Follow-up visit to check compliance.
Criminal law:	
Fixed penalty notice	• Registered person pays a fine and makes the necessary changes.
Simple caution	• Registered person admits offence and the caution is accepted.
Prosecution	• Registered person is prosecuted.
Civil enforcement:	
Conditions/urgent conditions	• To restrict activity to ensure the health, welfare and safety of people. • Follow-up visit to check compliance.
Suspension of registration/urgent suspension of registration	• Provider and/or manager implements the necessary changes to become compliant so temporary restrictions can be lifted. • Follow-up visit to check compliance.
Cancellation/urgent cancellation of registration	• Provider and/or manager is no longer registered to carry on regulated activities.

11.81 The regulatory response is, in part, determined by the provider's reaction to a finding of non-compliance. They are required to submit a report setting out how they need to achieve compliance and the action required. This is assessed for specificity, measurability, achievability, relevance and the time for implementation. If not satisfactory, providers will be asked to present a revised report. Implementation is then monitored by inspection:

> *... except where we can gather the necessary information to provide assurance through a desktop review.*[68]

11.82 This framework represents a change of approach from the one that applied at the time of the Inquiry's oral hearings and before. Previously, the CQC had looked in its reviews for evidence of compliance. The change of focus was opposed by the majority of respondents to the

68 *Judgement Framework*, CQC (April 2012), page 19, www.cqc.org.uk/sites/default/files/media/documents/20120321_final_judgement_framework_for_publication.pdf

consultation on the new framework on the grounds that it would be biased and negative and would lead inspectors to seek out non-compliance, rather than taking a holistic view and providing helpful information to the public. The CQC rejected the idea on the grounds that these are arguments justifying the status quo. They undertook to describe compliance when it was seen, thus ensuring balanced information for the public. They pointed out that the requirement is to be compliant with the regulations, not each and every prompt in the CQC guidance.[69]

Initial registration processes

11.83 Because of the time pressure referred to above, the CQC had to devote most of its resources to ensuring that existing providers were registered in a timely fashion to avoid breach of the legislative requirements.

11.84 NHS trusts were given a window during which they could be registered, subject to conditions, even if they were not fully compliant with the statutory standards. Between December 2008 and January 2009, provider trusts were required to submit applications for registration from April 2009, solely by reference to their compliance with the regulations on healthcare associated infections (HCAIs).[70] These applications were reviewed against other information held on the organisation and supported by inspections.

11.85 For the year beginning April 2010, applicants were required to declare their compliance against all 16 essential outcomes. Where there were declarations of non-compliance with some standards, or doubts resulting from other information about compliance, the regional teams reviewed and risk assessed those organisations in conjunction with other organisations such as Monitor and "sought further assurance of compliance, including site visits".[71] During the first year, approximately 40% of trusts informed the CQC of concerns about meeting one or more outcomes. Where the CQC was satisfied that a trust would be able to achieve compliance within a reasonable time, registration was granted without conditions. Where it was thought necessary, "compliance conditions" were imposed.

11.86 Approximately 22 trusts, including the Trust, were registered with conditions. Of these, three had declared full compliance but were assessed as non-compliant by the CQC. In view of the number of trusts that declared non-compliance, this might be thought to have been a rather small number, but Amanda Sherlock explained:

69 See *Response to Our Consultation Proposals for the Judgement Framework and Enforcement Policy*, CQC (March 2012), page 12–13, www.cqc.org.uk/public/sharing-your-experience/consultations/judgement-framework-and-enforcement-policy-consultation
70 Sherlock WS0000032283–5, paras 19–21
71 Sherlock WS0000032286, para 24

The imposition of conditions was taken very seriously by trusts and the Department of Health, so we did not want to be disproportionate and impose conditions on 40% of Trusts – in some cases this would have been like using a sledgehammer to crack a nut."[72]

Operational methods

The "field force model"

11.87 The CQC works through a "field force model" in a regional structure in which teams are based that focus on the compliance of a defined number of organisations. There are approximately 900 inspectors and registration managers who are responsible for assessing registration applications and monitoring compliance thereafter. They are supported by 170 analysts and 360 customer service staff.[73] The intention of the model is that inspectors are generic and may have in their portfolios any type of organisation regulated by the CQC, whether it be an NHS healthcare provider, an old people's home, or an independent healthcare provider.

11.88 Dr Andrea Gordon, the Regional Director for West and East Midlands, told the Inquiry about how the model was developed in her region.[74] In 2009, she managed four area managers who were responsible for overseeing regulatory activities in their areas. There was a separate team processing registration applications. Each area manager had local area managers reporting to them, and below the local area managers was a team of inspectors. Therefore, at this stage the generic concept for inspectors had not been promulgated.

11.89 Taking as an example the area within which the Trust fell (Shropshire, Stafford and Stoke), the area manager had line management responsibility for three local area managers. The local area manager for Stafford had a team of about seven inspectors, all from a CSCI background, and one healthcare assessor, who was responsible for oversight of the Trust.

11.90 In May 2010, a field force restructuring took place which resulted in the removal of the local area manager posts; some were promoted, and others opted for redundancy. It was at this point that inspectors were given a generic caseload, regardless of their previous background. Dr Gordon observed:

In practice we found that some staff were more keen to embrace a new way of working than others.[75]

11.91 After this restructuring, Dr Gordon had eight compliance managers managing between eight to 12 inspectors. The registration team remained separate, albeit with different personnel.

72 Sherlock WS0000032287, para 26
73 Sherlock WS0000032277, para 6; Sherlock T85.3–4
74 Gordon WS(2) WS0000040436, paras 2–8
75 Gordon WS(2) WS0000040438, para 6

One of the compliance managers was responsible for Stoke and Staffordshire and managed 10 inspectors.

11.92 Inspectors are on the whole "generalists", but according to the CQC have access to a wide range of expert assistance and advice should this be necessary. As an example Ms Sherlock cited the Dignity and Nutrition Inspections, commissioned by the Secretary of State, which are carried out by teams of practising nurses, professional regulators and "experts by experience". "Experts by experience" are persons with experience of using a service or in communication, who are recruited to assist inspectors by observation of interaction between patients and staff, and by themselves talking to patients, staff and management.[76]

11.93 It is thought that bringing in expertise where necessary ensures that the best quality up-to-date advice is available. There is also a panel of national professional advisers.[77] They are available to advise on the preparation for responsive reviews and inspections. In addition the CQC uses associate specialists to assist with visits. They are generally practising clinicians. Ms Sherlock observed that some at least on the list of experts inherited from the HCC were no longer in practice, something she found surprising.[78]

11.94 Ms Sherlock, in justifying this generalist model, stated that:

> *It is simply not possible with the resources available to have sufficient inspectors who are experts in each type of organisation. However the inspectors are professional regulators.*[79]

11.95 She said:

> *It is important to have a matrix approach to sharing information but with personal responsibility on individual inspectors for decisions about services within their portfolios.*

11.96 Each inspector has approximately 50 services in his or her portfolio, but typically not more than one NHS hospital trust.[80] However, as at the Trust, one NHS trust can have more than one site. She anticipated that once primary medical and dental care services had been added to the workload, an inspector's portfolio might increase to 60 services. She acknowledged that this was a workload about 20% higher than each HCC inspector had had and that this could create difficulties. She suggested that inspectors would become increasingly reliant on information provided by service users.

76 Sherlock WS0000032337, para 160
77 Sherlock WS0000032289, para 32; AS/7 WS0000032749
78 Sherlock WS0000032291–92, para 37
79 Sherlock WS0000032294, para 45
80 Sherlock WS0000032293, para 45

11.97 Dame Jo Williams recognised that resources did not allow for more inspectors at the moment and that, "If CQC had more resources available to it my priority would be to recruit more inspectors".[81]

11.98 She qualified this statement in her oral evidence:

> *What I'm saying is that at the moment we have registered NHS independent healthcare, social care, and more recently we're concluding the registration of dentists. And we know that our frontline staff have ... the workload of about 50 cases. We are due to register general practice. So the question in my mind is ... will we have sufficient resources to have that spread ... And we haven't done that analysis yet ... it may well be that through risk analysis we can take a lighter touch with some of those organisations that we are registering and monitoring, so that may help us. We're still, I'm sorry to keep saying this, but relatively new. So we are challenging ourselves all the time to say, "Are we making the very best use of public money? Are there further efficiencies that we can make to improve our performance?" But if at the end of all that a conclusion is that we can do no more with the resources we have, then we will build a case. But we're not quite there yet.*[82]

11.99 The use of the "field force" model has meant that the CQC do not have a central, specialist investigations team of the type the HCC had and which undertook the investigation into the Trust.[83]

11.100 Ms Bower told the Inquiry:

> *At the outset I was open-minded as to whether the investigation team should continue. However Baroness Young was very clear that in her opinion a mature regulator with proper legal powers, such as those that CQC had, did not need an investigations team and should be able to move quickly to deal with any problem at an early stage.*[84]

11.101 That decision was made by the Board in December 2009.

81 Dame Jo Williams WS0000032083, para 54
82 Dame Jo Williams T84.157–158
83 Wood WS0000025071, para 179
84 Bower WS(2) WS0000037367, para 17

11.102 This development has been fiercely criticised by Dr Heather Wood, who led the HCC investigation into the Trust, and later worked for the CQC until August 2010. She commented:

> *... if the decision to investigate Mid Staffs had been in regional hands or if there had been a risk summit with the SHA and other parties as happens now, the investigation would almost certainly not have taken place.*[85]

11.103 She was concerned at the generalist approach for a number of reasons:

- She considered that inspectors not familiar with the care environment and clinical requirements could be too easily reassured or misled.
- Training had largely been given to inspectors by generalists.
- She feared that unskilled inspectors would not give confidence to whistleblowers to come forward.
- There was a danger of their missing or underestimating problems.
- The scale of the CQC's responsibilities meant that its capacity to inspect at all was limited, let alone to do so effectively with clinical services.[86]

11.104 She added in her oral evidence

> *... I find it troubling that you might send an ex-social worker and, I'm sorry, I don't mean that as a derogatory term at all, but into an operating theatre to assess what's happening – well, it probably wouldn't be exactly in the theatre but perhaps in the recovery area. I just feel inspection per se will not deliver unless you have the right people doing it with the right tools, and I would also say, I think, with the right mindset.*[87]

11.105 Amanda Sherlock disagreed with this pessimistic viewpoint. She argued that CQC inspectors had the same access to specialists as did the HCC and although HCC inspectors may have had NHS backgrounds, no one inspector can be trained in all specialisms. Further, she pointed out that wherever possible, training is now given by in-house experts in the particular subjects.[88]

11.106 Dame Jo Williams disagreed that disbandment of the central investigation team meant that its capacity to detect failings had been diminished. She pointed to the CQC's various methods of obtaining information and intelligence, including Quality and Risk Profiling (QRP), mortality analysis, information from the National Patient Safety Agency (NPSA), and the CQC's helpline. The absence of a central investigation team did not make it less likely that information indicating failings would be picked up.[89]

85 Wood WS0000025071, para 179
86 Wood WS0000025072–074, paras 180–192
87 Wood T81.162–163
88 Sherlock WS0000032295, para 46
89 Dame Jo Williams T84.124

Training

11.107 In 2010, when it was decided to move to a generic model of inspection, a training programme was introduced to prepare inspectors for this extended role.[90] Dame Jo Williams told the Inquiry that inspectors were trained to a set of standards.[91]

11.108 Cynthia Bower told the Inquiry that generic inspectors could make judgements about the core expectations within many of the standards and were in any event trained in those issues:

> *... if ... the premise of your model is that ... the inspector who goes in has to be an expert in that particular field of medicine or surgery, for example, well, then, we would never develop an inspection workforce that could cover every possible range. What we're saying is that there are core expectations that are inherent within the essential standards that one could make – anyone could make judgments about dignity, engagement, complaints, cleanliness of environment, people are trained in those issues. If we need to look at specific areas of clinical or indeed expertise in social care, then there are experts that we can draw on to advise us about how we construct inspections, to go with us on inspections, to advise us how judgments are made ...*
>
> *... we would try and ensure that there are fundamentals in appropriately conducting your job, that all staff are trained in. So, for example, how you seek the views of people who might have communication problems. There are tools that we use, for example, that help us observe care between people with dementia and their care givers, so that, for example, people with dementia wouldn't find it easy to talk to an inspector about whether they were being cared for appropriately, so we've developed observational tools that assist them in looking at that in a structured way so that a greater understanding is gained of what that interaction is looking like.*[92]

11.109 The evidence from a front-line inspector at the CQC did not suggest that any extensive training had taken place. Amanda Pollard had worked as a specialist HCAI inspector at the HCC, and then at the CQC, immediately after being transferred from the HCC. At the HCC she had received training in the role, which included videos of other inspectors undertaking their work. They had access to expert support during inspections, which were usually conducted by inspectors working in pairs.[93] While continuing in the same role at the CQC she did not require any further training as she was experienced in this role by then.[94]

90 Gordon WS(2) WS0000040438, para 6
91 Dame Jo Williams WS0000032069, para 27
92 Bower T87.29–33
93 Pollard T137.19–21
94 Pollard T137.25–26

11.110 In August 2010 the breakup of the HCAI inspection team was announced. She was sufficiently concerned to write directly to the Chief Executive in protest at what she saw as being lost:

> *I feel that something was lost, because especially with hospitals, it's just not realistic for the rest of the inspectors to have been trained to the level that we were trained, but the new field force model was that it was generic, everyone was to be generic, and I just thought that was just a waste.*[95]

11.111 Asked about the concept of a generic "professional regulator", Ms Pollard had this to say:

> *I don't feel very professional sitting here ... they're saying that everyone should be able to use the regulations and be able to go out and assess in the same way. That works to an extent. I think in order to be able to do that, you have to properly train people in what you're going to assess. And I think there's also issues of, you know, staff morale that people have built up backgrounds of experience and their CVs in particular specialisms, and it is demoralising people to not have that recognised and to be told that they're just generic.*[96]

11.112 She was then transferred to assist in the registration process by assessing applicants, but received no training for that purpose.[97] There was training offered when she became a compliance inspector in October 2010. However she described it as "appalling" and said that those attending were laughing at how bad it was.[98] She disputed the evidence of Dame Jo Williams that there was training to a set of standards.[99] She sought to make up for what she saw as deficiencies in her training by soliciting help from colleagues more experienced in the social care sector.[100] The result, according to Ms Pollard, was that initially it was not clear to her what her role was as an inspector.[101] In her experience of about 20 inspections she had not seen any use of specialist assistance.[102] It is only fair to bear in mind when considering Ms Pollard's evidence that she did not have an NHS trust in her portfolio.

11.113 Ms Pollard's concern about the lack of training is a continuing one. Following the issues that have arisen in the now well-known case of Winterbourne View, Ms Pollard told the Inquiry that, although her own line manager had held a team meeting to discuss that case and how they would have dealt with it, she did not believe this had been a widespread exercise:

95 Pollard T137.31
96 Pollard T137.32–33
97 Pollard T137.36
98 Pollard WS0000078121, para 31
99 Pollard WS0000078121, para 33
100 Pollard T137.43
101 Pollard WS0000078122, para 36
102 Pollard WS0000078122, para 35

> *It is of real concern to me that as inspectors we have had no real training about how we could potentially spot when this was happening within a provider setting … In absence of such training or reflective learning I do not think that the CQC are able to assure themselves that I, as an inspector, would spot another Mid Staffordshire or Winterbourne View and this is a real risk.*[103]

11.114 Kay Sheldon OBE, a CQC Commissioner whose evidence is considered in more detail elsewhere, told the Inquiry that she had concerns about training being offered to inspectors. She accompanied an inspector on a visit to a large acute hospital. The inspector told her she did not feel she had the knowledge or support to perform the task, including having to speak to the Chief Executive. On another visit to a care home it became clear to Ms Sheldon that the inspector had not received training, as a result of which she missed a number of issues.[104]

Inspectors' autonomy

11.115 The CQC model seeks to allow the inspectors to exercise independent judgement about what if any regulatory intervention is required, albeit in consultation with managers and colleagues. Amanda Sherlock explained:

> *One of our principles, when we were doing our workforce design and coming up with the roles and how we would discharge our responsibilities, is that we wished the frontline inspector to have as much professional autonomy in the way that they regulate the services on their portfolio as possible, with professional checks and balances to ensure that you didn't have regulatory capture or you didn't have overzealous regulation of individual providers.*[105]

11.116 Whatever degree of independence inspectors have, they do not work in isolation. They report to their compliance manager, who in turn reports to a regional director, who reports to Ms Sherlock. She chairs a Risk and Escalation Committee, which considers the management of risks brought to its attention.

11.117 There is also an intelligence system. In each region there is a regional intelligence and evidence manager (RIEM), a senior analytical adviser (SAA) and a number of regional intelligence and evidence officers (RIEO). In the centre is a central analytical team who support projects. The RIEOs have a portfolio of organisations in their locality.

11.118 The system is intended to allow inspectors to combine the product of nationally obtained intelligence with their own local knowledge to inform their judgements. Each region has an "indicative schedule" of activity which is based on risk. It is intended that just over half of

103 Pollard WS0000078132, para 70
104 Sheldon WS0000078493, para 56
105 Sherlock T85.123

inspectors' time (55%) is taken up with responsive reviews, and the rest (45%) allocated to planned, routine reviews.[106]

11.119 There is an organisational expectation that when the QRP risk dial shows red the local inspector would decide to hold a responsive review.[107]

11.120 The CQC expected planned reviews to take place at each organisation within not more than two years from registration. Ms Sherlock told the Inquiry that they are very resource intensive and many have been pushed back because of the demands for responsive reviews. They are being postponed after taking account of the risks involved in individual cases.[108] She told the Inquiry that a "crunch point" was likely to be reached, in that not all planned reviews required before the end of 2011–2012 were likely to have taken place by then. Therefore the CQC was considering how it could "reduce the burden" of such reviews.

11.121 The CQC acknowledged the risk of local inspectors becoming too embedded in the culture of a particular provider with which they had become familiar, and sought to meet this by rotation of staff, by requiring more than one inspector on NHS inspections and by review by regional risk panels.[109] Richard Hamblin, Director of Intelligence at the CQC at the time of giving evidence, thought there was an opposite risk for central teams of presuming that everything at a provider was wrong because they had been called in.[110]

Intelligence, information and risk analysis

11.122 The CQC collects information from a number of sources and the main ones are set out below.

Patient and user voices

11.123 The CQC obtains information from:

- Local patient groups;
- Patient feedback;
- LINks;
- Service user groups;
- Individual patient contacts, via the internet, or contact with local managers and inspectors;
- Overview and Scrutiny Committees.[111]

106 Sherlock WS0000032354, paras 213–214
107 Hamblin WS000031043, para 143
108 Sherlock WS0000032355, para 215
109 Sherlock WS0000032354, para 213
110 Hamblin T86.176
111 Hamblin WS0000031019 paras 53–67

Complaints

11.124 Information received from and about complaints is somewhat haphazard. Details of complaints are received from the Parliamentary and Health Service Ombudsman (PHSO) (see below), but as the CQC have no power to determine and investigate individual complaints as such, they are by no means aware of all complaints. However some complainants do contact them to inform them of their concerns. Indeed, although the CQC cannot itself resolve complaints and does not wish to have the power to do so, it does via its website encourage the public to tell it of the substance of any complaint made, which will then be fed into the QRP.[112]

11.125 The CQC's Head of Operations, Amanda Sherlock, told the Inquiry:

> *CQC does not actively canvas for views other than through the various consultations we run on our processes and fees etc. However if complainants or representative organisations provide information to CQC via any of the channels of communications. CQC will use this information.*[113]
>
> *CQC does not routinely ask for trusts' complaint handling information – this could dilute the accountability of trust boards to consider and assure themselves that complaints are well handled and that findings feed back into organisational learning, … we do not want any dilution of responsibility by CQC taking on audit or quality assurance functions. This is where the power of a good complaints system lies.*

11.126 This evidence might have been read as meaning that the CQC did not want to receive complaints to avoid diluting accountability, but it has assured the Inquiry that what was meant was that it did not want the power to resolve complaints for this reason.

11.127 Dr Gordon said:

> *CQC does not deal with complaints per se but any relevant information we do receive is built into our analysis through the QRP.*[114]

11.128 Mr Hamblin said that the substance of complaints was not "routinely" fed into the QRP and pointed out there was a danger of being swamped with too much information. He said there were no current plans to use the substance of complaints as the complaints system was currently set up. He thought a mandated return from trusts about patterns of complaints, how they were dealt with and outcomes would be useful. He agreed that it was worth looking into whether some form of filtering system could be adopted to allow the CQC to

112 Sherlock WS68 WS0000032304
113 Sherlock WS73 WS0000032306
114 Gordon WS(2) WS0000040458–459, para 78

receive information about complaints in a useful form.[115] Both he and the CQC in its closing submissions suggested that the Inquiry might consider recommending such a return.[116]

11.129 There is currently no system for the Independent Complaints and Advocacy Service (ICAS) to notify the CQC of the complaints it is receiving or information about them. Further, it appears that POhWER, which provides the ICAS service for the West Midlands area, has offered to outline training and expertise that they could offer to the Trust in an effort to improve the experience of patients. None of these offers were followed through aside from a single customer care training session, delivered free of charge.[117]

11.130 This evidence revealed a somewhat passive attitude on the part of the regulator. While it accepts that complaints information is valuable, it essentially reacts to information it receives rather than ensuring it has reliable access to all useful complaints information relevant to assessment of compliance. Clearly this is something the CQC should take up as a matter of urgency. There is no need for it to wait for the implementation of an Inquiry recommendation. For it to have an incomplete view of complaints generally or by reference to each organisation it regulates is of concern, as these are clearly a prime source of early indications of concerns. The lesson of Stafford is that complaints were being made that in their substance indicated serious systemic failure, but these were not being relayed to regulators.

11.131 There are several "channels" through which the CQC could actively seek such information and it should do so. Local relationship managers asking trusts for granular information would be a good start. If there are bureaucratic or legal obstacles to this occurring they should be removed. However, it is in fact acknowledged that the CQC has the power to ask for this information.

11.132 Ms Sherlock's evidence might have been understood to mean that this is not done because it would dilute the accountability of Trust Boards.[118] This is not tenable: collection of information does not equate with assumption of primary responsibility for acting on it, and therefore it is to be welcomed that the CQC have explained to the Inquiry that this is not what was meant. Without a comprehensive range of complaints information from each provider, a valuable source of information from those with actual experience is lost. An organisation which should be putting the patient experience at the top of its priorities would be failing in its duty if it did not take such an elementary step. Monitoring in a systematic way information derived from complaints and the complications to be derived from them does not and should not be regarded as diluting the responsibility and accountability of trust boards. It is suggested that if this process were undertaken at a local level by engagement with trusts, adopting a culture of openness, then the burden should be a light and effective one.

115 Hamblin T86.93–96
116 CL0000000559–560, *CQC Closing submissions,* paras 271–273
117 POhWER WS(Provisional) – POW00000000010
118 Sherlock WS0000032308, para 77

Ombudsman

11.133 The CQC does receive information from the PHSO. This consists of decisions and a limited amount of information about those second stage complaints she determines, including the recommendations for remedial action. This allows the CQC to monitor whether that action is in fact taken. There are regular meetings between the CQC, the PHSO and the Patients' Association (PA).

11.134 This is all to the good, but, as the CQC acknowledges, the PHSO only sees a small minority of complaints and therefore offers a necessarily incomplete picture. The steps suggested above would result in a more comprehensive picture being available.

Overview and scrutiny committees

11.135 The CQC runs "sounding board events" for local councillors and officers involved in the Overview and Scrutiny Committees (OSCs) as well as FT governors. The OSCs are said to be free to provide information via an internet link. Clearly there is more work to do here to develop this potentially valuable information resource.

Foundation trust governors

11.136 Governors provide 12% of the internet submissions to the CQC, which is regarded as a low proportion.[119] This is attributed to low awareness among this group of the CQC. Steps are being taken to increase this awareness. It would surely not be difficult via each registered body to send a personal letter to each governor inviting them to submit relevant information about any concerns to the CQC.

Patient Safety Alerts

11.137 Patient Safety Alerts are fed into the QRP, but, as at December 2011, the evidence was that there was no routine follow up of compliance, unless the information suggested non-compliance with an essential standard. The CQC attributed this in part to their not having relevant expertise, particularly in relation to the safety of equipment. It argued that to take on such a role would deflect it from its core activities.[120]

11.138 A report was issued by Action Against Medical Accidents (AvMA) in February 2010 on the rate of non-compliance with safety alerts from the NPSA.[121] Following its publication, The CQC met AvMA and then wrote to all those organisations who were indicated on the Central Alert System as having failed to implement 10 or more alerts by the NPSA since June 2004. The CQC told these trusts that when assessing compliance with outcomes 4, 9, 10 and 11, the CQC

119 Sherlock WS0000032309, para 83
120 Sherlock T85.85.86
121 AVMA0001000043, *"Adding Insult to Injury": NHS Failure to Implement Patient Safety Alerts* (February 2010), AvMA

inspectors would be looking to see whether the trust had taken action in response to its alerts.[122]

11.139 However, inspectors are only able to assess whether there has been a response to an alert as opposed to the appropriateness of that response, as they lack expertise, for example in relation to the safety of equipment.[123] Ms Sherlock accepted this was an area for the system to explore.[124]

11.140 As the NPSA's information about whether a Trust has declared compliance with an alert has been fed into the QRPs, it is difficult to see why at least this amount of information should not be used in terms of following up that compliance. If an alert is genuinely about safety it is difficult to understand how this cannot relate to an essential standard.

11.141 There appears to be a regulatory gap here. While the NPSA issued the alerts, the CQC had a limited role to play unless the alert was relevant to compliance with an essential standard. If alerts are to be a significant contribution to patient safety they should be complied with absent good reason not to do so. There needs to be a clear responsibility imposed on an identified regulator to review decisions not to comply with alerts and to oversee the effectiveness of any action required to implement them. The CQC seems the obvious, if not the only, regulator available to take on this task, certainly in relation to alerts that are not about issues relevant only to medical devices within the jurisdiction of the Medicines and Healthcare products Regulatory Agency (MHRA).

11.142 At the end of the oral hearings it was not clear what new arrangements were going to be made in this area following the absorption of the NPSA's functions into the NHS Commissioning Board. It will be important that information sharing regarding Patient Safety Alerts continues after this transfer of the NPSA's functions in June 2012.

Incidents

11.143 There is a statutory obligation on providers to report certain categories of incident to the CQC:

- Death of a service user occurring whilst services were being provided in the carrying out of a regulated activity or as a consequence of the carrying on of a regulated activity;
- The death or unauthorised absence of a service user who is detained or liable to be detained under the Mental Health Act 1983;
- Injury to a service user which either: (i) results in impairment, changes to the structure of a service user's body, prolonged pain, prolonged psychological harm, or a shortening of

122 Sherlock WS0000032311, para 87
123 Sherlock WS0000032311, para 87
124 Sherlock T85.86–87

life expectancy; or, (ii) which requires treatment to prevent death or any of the outcomes specified in (i);
- Any abuse or allegation of abuse in relation to a service user;
- Any incident which is reported to, or investigated by, the police (although this does not apply where the service provider is an English NHS body);
- Any event which prevents, or appears likely to threaten to prevent, the service provider's ability to continue to carry on a regulated activity safely, or in accordance with the registration requirements, including:
 - An insufficient number of suitably qualified, skilled and experienced staff;
 - An interruption in the supply to premises owned or used by the service provider for the purposes of carrying on a regulated activity of electricity, gas, water or sewerage where that interruption has lasted for more than a continuous period of 24 hours; or
 - The failure or malfunctioning of fire alarms or other safety devices in the premises that has lasted for more than a continuous period of 24 hours.[125]

Failure to comply with this obligation is an offence.

11.144 This obligation has been fulfilled in practice by a report to the NPSA which passes on the information to the CQC. There is no statutory obligation to report "near misses". The NPSA passed on such reports of these that it received and the CQC does not consider the absence of a statutory obligation a weakness in the system. The CQC does consider the reports passed on to it.[126]

11.145 Until a clear definition of "near miss" is arrived at that allows for consistent practice in reporting, it is not fruitful to consider imposing a requirement of reporting this category of incident to the CQC.

Serious untoward incidents

11.146 Some Strategic Health Authorities (SHAs) pass on serious untoward incident (SUI) reports to the CQC, but others do not. There is no requirement for them to do so.[127] While such information should in the past have come to the CQC via the NPSA, it is likely that it would be more rapid and accompanied by other useful information if SHAs were to do this as a matter of routine.

NHS Litigation Authority ratings

11.147 The primary function of the NHS Litigation Authority (NHSLA) is to indemnify NHS organisations against clinical negligence claims (discussed in more detail in *Chapter 15: Risk Management and the NHS Litigation Authority*). As part of this role, the NHSLA assesses

125 The Care Quality Commission (Registration) Regulations 2009, regulations 16–18, www.legislation.gov.uk/uksi/2009/3112/contents/made
126 Sherlock WS0000032312, para 89
127 Sherlock WS0000032356, para 218

organisations against its own risk management standards. The CQC has mapped the NHSLA data onto its own essential standards. It does not use the NHSLA's overarching judgement on providers, but instead focuses on the underlying data, for example information on how well organisations are set up to comply with NICE guidance. In November 2010, more than 100 different indicators derived from the NHSLA assessment were employed by the CQC.[128]

Inquests

11.148 On occasion CQC staff attend inquests, but this is not frequent. Remarkably, it was only over the course of this Inquiry that the CQC became aware that summaries of Rule 43 letters are published annually by the Ministry of Justice.[129] As a result of their attendance at the Inquiry where this issue was raised, the CQC are now able to consider how to incorporate this knowledge into their knowledge base.[130]

11.149 They are not notified directly of upcoming healthcare-related inquests and this should be required – either by trusts or perhaps more usefully by coroners.

NHS Choices

11.150 The CQC receives commentary on the performance of individual trusts from NHS Choices.[131] Patients and their relatives can leave comments about their experience on the NHS Choices website, and an edited data feed is provided to the CQC. It varies in quantity between 350 and 600 comments per month.[132]

Mortality outliers

11.151 The CQC receives individual mortality alerts from the Dr Foster Unit (DFU) at Imperial College (discussed in more detail in *Chapter 5: Mortality statistics*). The DFU analyses a range of data, issuing mortality alerts where it detects a doubling of the odds of death at a particular hospital for a specific diagnosis or procedure (43 diagnoses and 79 procedures are currently assessed). An alert is only generated where the probability of a false alarm is less than 0.1%.[133] The CQC also generates its own alerts based on an analysis of the national Hospital Episodes Statistics system (HES), which aims to identify concerning trends for specific conditions or procedures over time. In this case, alerts are generated where an organisation's mortality or emergency readmission rate has crossed a predetermined threshold of difference from the expected level.

128 Hamblin WS0000031018, para 48
129 Sherlock WS0000032317, para 107
130 Sherlock T85.112–113
131 Sherlock WS0000032318, para 108
132 Hamblin WS0000031019, para 54
133 Jarman WS0000042781, para 112

11.152 A mortality and emergency readmission panel meets monthly to consider the outlier alerts. The mere generation of an alert (of either type) does not demonstrate that services at the offending trust are poor. The outliers are instead designed to stimulate local inquiry into potential problems that may have caused a rise in mortality. The panel will consider each alert and determine whether there is clear evidence that it has been caused by a data anomaly or local factors not linked to the standard of service. Where there is no reasonable certainty that this is the case, a letter is sent to the trust in issue, and its response monitored at subsequent meetings.[134]

Staff surveys and feedback

11.153 The CQC commissions an annual staff survey undertaken by NHS trusts and PCTs. The survey includes data directly relevant to the quality of care such as information on hygiene, staffing, training and the reporting of serious untoward incidents. The survey is wholly anonymous. Apart from a free text "any other comments" section, the survey consists of closed questions with many answers being scaled on a range of 1 to 5. Responsibility for the survey has recently been handed back to the DH.[135]

Quality Risk Profile

11.154 The QRP tool employed by the CQC facilitates its approach to the regulation of healthcare services in two ways. Firstly, the QRP acts as a repository for all relevant information held by the CQC on registered providers. As well as retaining information, the QRP also presents an analysis, called a "risk estimate", of the likelihood of an organisation's potential non-compliance with the essential standards of quality and safety, the key benchmark by which the CQC judges a provider's performance. The QRP does not provide a definitive judgement on an organisation's compliance, but is instead designed to indicate areas of concern and suggest areas of potential investigation.[136]

11.155 The CQC refreshes its QRP for each NHS service provider every month. In the event that the risk estimate for a trust changes, an alert will be generated automatically, causing the inspector assigned to the trust to review the QRP and make any necessary enquiries. Data from QRPs is also analysed to identify trends at a regional level.[137]

11.156 Richard Hamblin, Director of Intelligence at the CQC at the time of giving evidence, explained that whilst the QRP was based on the HCC Annual Health Check (AHC), the CQC sought to go further:

134 Hamblin WS0000031036–38, paras 117–123
135 Hamblin WS0000031014, paras 31–32
136 Hamblin WS0000031026, paras 79–80
137 Sherlock WS0000032323, para 121.2

... The maths that underpins it, and the stats underpinned it did [grow out of the Annual Health Check]*, but it had a ... broader view as well that we wanted to encapsulate something, what was called the organizational risk profile which was* [what] *the Healthcare Commission held at a local level about the sort of local qualitative information ... We wanted to get that in there as well.*

... I'm always slightly nervous of using measures of ... governance or management or organisation, because ... they can get a little abstract, a little tangential. There's a ... wonderful line about clinical governance that what it did in its first three years was create a lot of committees but not a lot of improvement. And ... it feels to me there's a slight element of that if you start looking at trying to measure governance and management rather than trying to get a sense of what's actually going on on the ward or in the A&E department, in the doctor's surgery.[138]

11.157 The QRP is made up of both quantitative and qualitative data. As at February 2011, the CQC drew upon 46 sources of quantitative data. The list below records the sources from which the CQC gathered the most information, and the number of data items collected:

- NPSA patient environment action team (PEAT) inspections – 51, 764 items;
- DH information governance toolkit – 21,639 items;
- NHSLA risk management standards – 14,687 items;
- CQC NHS staff survey – 11,107 items;
- Counter Fraud and Security Management Service compliance data – 8,402 items;
- CQC NHS adult inpatients survey – 5,542 items;
- CQC Mental Health Act data – 5,392 items;
- The Information Centre hospital episode statistics – 4,866 items;
- The Information Centre vacancy survey – 4,683 items;
- 36 other sources – 28,648 items.[139]

11.158 Mr Hamblin accepted that the effectiveness of the QRP depended on a combination of the effectiveness of the sources of information and the way in which that information is put to use by the CQC. He continued:

I think it's important not to get to hung up on the total number of data items because the way the data items work is driven by probably three or four things to a greater extent than just the pure number of data items that are there ...

So you couldn't from this list look at it and say in a simplistic way, the PEAT scores at the top have ten times as much power as the NHS outpatient survey ...

138 Hamblin T86.36–37
139 RH/2 WS0000031060; Hamblin WS0000031012, para 23

... I think [the sources of data] *are imperfect and we recognise the imperfections and we recognise the potential weaknesses there, which is why we come back to, again, that it's not trying to derive a judgement from this information, it is recognising this is what we have and it's the best at the moment, but we always look for better stuff to put in.*[140]

11.159 The CQC collects qualitative data from a variety of sources, including information from other supervisory bodies, from local stakeholders such as patient groups, from inspectors and from patients themselves. Along with the NHS Choices system (discussed above), patients can provide feedback direct to the CQC through its Customer Relationship Management system and its National Contact Centre. Information is sought from bodies such as the Audit Commission and the Health and Safety Executive (HSE), as well as from the media.[141]

11.160 As set out above, the main focus of the QRP system is to relate data to the 16 key outcomes in the essential standards. Each piece of data is therefore assessed and mapped onto the outcome (or outcomes) to which it is relevant. The data is also given a weighting in relation to three different criteria:

- Strength – how closely the data relates to the outcome to which it has been mapped;
- Patient experience – the degree to which the data impacts on or reflects the experiences of patients;
- Data quality.

11.161 For quantitative data, the weighting is predefined, but for qualitative data each piece of information is analysed and weighted by the local intelligence analysis team as it is received. The process of weighting is not subject to formal audit or review.[142]

11.162 All data is then statistically analysed to compare the actual performance with the performance expected by the CQC. For quantitative data, expected performance is determined by taking an average of the NHS organisations measured, sometimes adjusted to take into account factors beyond the organisation's control, and sometimes adjusted to take account of local circumstances in a particular geographical area. Scores are then awarded to the provider, with a score of more than +2 denoting "much worse than expected" performance, between +1.2 and -1.2 denoting "similar to expected", and a score of -2 denoting "much better than expected" performance. Qualitative data is simply assessed as being "positive" (attracting a score of -1) or "negative" (+1), though Richard Hamblin accepted that the CQC "are still learning how best to make use of qualitative data".[143] Aggregate scores are then determined for each

140 Hamblin T86.58–59
141 Hamblin WS0000031019–22, paras 53–67
142 Hamblin WS0000031027–29, paras 85–91
143 Hamblin WS0000031029–32, paras 92–102, quotation taken from para 102

outcome, producing a risk estimate on an eight-point scale ranging from "low" risk of non-compliance with the outcome to "high" risk.[144]

11.163 The QRP also displays information regarding a provider that is not directly related to the essential standards, in the following three categories:

- Inherent risk – the risk attributed to an organisation by virtue of its case mix, where factors such as high complex surgical volumes lead to a higher risk;
- Population risk – the risk created by features present in the local population that have been shown to affect care outcomes and access to care, such as deprivation and overall population health;
- Situational risk – the risk attributable to the provider by virtue of its organisational context, including information about the trust's financial situation, vacancy rates, governance measures and risk management procedures.[145]

11.164 There are a number of limitations with the QRP:[146]

- A degree of self-assessed or self-declared data is fed into the profile;
- The "dials" are set in a way which means there has to be considerable divergence before crossing the amber threshold;
- Some outcomes may have little information attached to them;
- The QRP rating is not intended to be a judgement on compliance, only of risk of non-compliance;
- It is not particularly sensitive to sudden deterioration and not expected to be. Its main use is for detecting patterns over a period of time which may not otherwise be detected;
- There is as yet no formal evaluation for effectiveness;
- It has not yet not been released to the public because it is not yet in a form where that is deemed appropriate, although it is intended in due course to do so.

11.165 The QRP is a considerable and sophisticated advance on the analytical methods previously available and its development should be encouraged. As the CQC recognise, it is, however, only a tool to assist in the assessment of risk of non-compliance, not a tool that can determine non-compliance in itself. It should not be regarded as a potential substitute for active regulatory oversight by inspectors. It is important that this is explained carefully and clearly as and when the public are given access to the information.

144 Hamblin WS0000031033, para 104
145 Hamblin WS0000031034, para 109
146 Hamblin T86.125–145

11.166 The QRP is currently made available to Monitor and trusts and this is not only desirable but an essential step on the road to integrating as far as possible all forms of information relevant to the quality of service being delivered.

Inspections and reviews

Planned reviews

11.167 As indicated above, planned reviews are intended to occur in each organisation within two years of registration. The Inquiry heard that 482 such reviews were carried out in 2010–2011 and 636 were planned in 2011–2012.[147] The actual frequency is determined by an assessment of risk at each location.

11.168 A planned review is of compliance with each of the 16 key outcomes and "may or may not involve a site visit."[148] However, in practice, currently planned reviews are highly likely to involve a visit to the site.[149] Ms Sherlock was questioned about the use of the term "inspection" to describe compliance reviews. She made it clear that an "inspection" did not necessarily mean that there had been an on-site visit, but could have meant that there was a review of systems and paperwork.[150]

11.169 A report is written and published after each review and the risk of the organisation is reassessed and included in an updated QRP.

Responsive reviews

11.170 A responsive review is a targeted review of one or more outcomes as a consequence of concerns about compliance with one or more of the essential standards. These can be raised from any source, such as complaints, or through direct contact with the provider.[151]

11.171 Once it is decided to hold a responsive review, a lead inspector is appointed to review the available QRP and any other available information. Specialists may be called in to assist or undertake visits.

11.172 As with planned reviews, the decision as to whether or not a site visit is required depends on a risk assessment and/or further information obtained from the provider. Information provided by the organisation by way of self-assessment (a provider Compliance Assessment) is checked against that from other sources, if available, and self-declaration is not accepted merely on

147 Sherlock WS(2) WS0000071746, para 15 correcting the figure of 257 given in her first witness statement (Sherlock WS0000032350, para 198) as a result of retrospectively updating CQC's information systems.
148 Sherlock WS00000032324, para 124
149 Sherlock WS0000032324–325, para 125; AS/35
150 Sherlock T85.61
151 Sherlock WS0000032326, para 130

trust in such circumstances. Dr Manjit Obhrai, Medical Director at the Trust at the time of this Inquiry, commented that he does not think the CQC's reliance on self-assessment offers a very robust scrutiny.[152]

11.173 Ms Sherlock did not accept this criticism:

> *... it fails to acknowledge the difference between self assessment under the old system and the new system which takes into account providers' assessment as part of the information considered in reviews of compliance, which are also informed by CQC's own risk assessments (using QRP) and findings on inspection ... Although CQC's guidance is to require information to be submitted in Provider Compliance Assessments to be triangulated, the practice in some instances, during planned reviews, is that the information supplied by providers ... in relation to particular outcomes is accepted because CQC has no other evidence to suggest non-compliance in relation to that Outcome.*[153]

11.174 She said this largely related to independent healthcare and social care providers, where the QRP is not as populated with information as that for NHS organisations.

11.175 She accepted that this raised:

> *... a significant issue as to the effectiveness of planned reviews as a tool and whether CQC should move further to an approach of intervening and inspecting only when it receives actual evidence of non-compliance.*[154]

11.176 Visits are only carried out where "they are genuinely the most efficient and effective way to gather evidence."[155]

11.177 They are usually unannounced. Which parts of a hospital are visited will depend on the concerns, but where these relate to the whole organisation inspectors are advised to select areas where people are particularly vulnerable.[156] The intention is that inspectors spend 50% of their time on the visit observing care processes, 30% talking to service users and the rest of the time talking to managers and staff.[157]

152 Obhrai WS0000006378, para 85
153 Sherlock WS0000032329, paras 137–138
154 Sherlock WS0000032329, para 138
155 Sherlock WS0000032332, para 144
156 Sherlock WS0000032334, para 150
157 Sherlock WS0000032335, para 151

Frequency of reviews

11.178 The CQC displayed uncertainty in its evidence about the number of reviews or inspections it had carried out. In its Provisional Statement, it informed the Inquiry that it had carried out 13,000 inspections in 2009–2010. In its Annual Report for 2010–2011 it announced it had carried out 15,220 inspections in all sectors. However in further evidence to the Inquiry Ms Sherlock stated that it had been discovered as a result of her preparing her further evidence that the correct figure was 7,368.[158] At the same time she was able to correct the figures in relation to planned reviews.

11.179 In July 2011 Cynthia Bower, as Chief Executive of the CQC, was quoted in an article in the *Health Service Journal* as promising inspections of all NHS trusts at least once a year, and that by "inspections" she meant "cross[ing] the threshold" rather than a purely paper-based exercise. She intended to seek additional funding for this purpose. In further evidence to the Inquiry she denied this represented a change of policy, but confirmed the gist of the report.[159]

11.180 Ms Bower also told the Inquiry that the intention of inspections would be to assess compliance with a key group of outcomes based on the nature of the service being inspected and the information the CQC had. It would not be intended to inspect an organisation against all 16 outcomes.[160]

11.181 Dr Andrea Gordon was asked if she would want to conduct planned reviews of all 16 outcomes if the resources were available to do so. She did not think that this would be required in the adult social care setting but:

> *... consideration around the NHS might be slightly different, because of the very complex nature of them ...*
>
> *THE CHAIRMAN: So is your answer to the question on consideration that you might be inclined, resources permitting, to have the 16 outcome review on a planned basis in an NHS Trust?*
>
> *A: Round the NHS? Probably more so than the adult social care setting. I think the aim is that whatever we can do that enables us to go in, step over the threshold of an organisation more routinely and more often, that's why we're reviewing our methodology, because the inspectors want to be out there, they want to be going into organisations. So whatever we can do that allows them to do that more swiftly and more routinely, then that's a good thing.*[161]

158 Sherlock WS0000071743, para 7 and WS0000071747, para 17
159 CB/1 WS0000067622
160 Bower WS(3), WS0000067618, para 7
161 Gordon T88.69

Investigations

11.182 Under section 48 of the Health and Social Care Act 2008, the CQC retains the power to conduct investigations as well as reviews (which are now to be called "inspections").[162] As indicated above, the CQC has no investigation team as such, but according to Ms Sherlock has established investigations on four occasions, including two of NHS hospital trusts: Barking, Havering and Redbridge University NHS Trust and United Lincolnshire NHS Hospitals Trust, both following the findings of compliance reviews.[163] Both investigations were announced in June 2011 and the reports of each were published in October and November 2011.[164]

11.183 Ms Sherlock told the Inquiry that instead of having an established team in the CQC they were able to assemble a "bespoke" team for each investigation including CQC staff and others from external partners.[165] She also pointed out that the investigations were concluded within about six months.

11.184 It is clear that the CQC did not want to follow the HCC model of an in-house team conducting investigations, which it thought took too long. Dame Jo Williams said:

> *In reaching this decision, one of our key objectives was to swiftly take action to resolve shortcomings and bring about change as soon as concerns were identified. Although very thorough, the investigations undertaken by HCC were simply too lengthy lasting 1 or sometimes 2 years. A lot can go wrong in that timescale. We therefore developed a new model for the CQC.*[166]

Triggered risk summits

11.185 Where concerns are identified that the CQC considers would benefit from the joint attention of other agencies, it will call a "risk summit". These have in the past been organised by SHAs. The purpose of the summits is to share information about an organisation, decide what action needs to be taken and avoid duplication of effort. This might include an unannounced visit by CQC inspectors accompanied by an inspector from the HSE.

162 Sherlock WS(4) WS0000077333, para 3
163 Sherlock WS(4) WS0000077336, paras 12–20
164 *Investigation Report: Barking, Havering and Redbridge University Hospitals NHS Trust: Queens Hospitals; King George Hospital*, www.cqc.org.uk/sites/default/files/media/documents/20111026_bhrut_investigation_report_final_0.pdf; and *Investigation Report United Lincolnshire Hospitals NHS Trust: Pilgrim Hospital*, www.cqc.org.uk/sites/default/files/media/documents/20111031__ulht_report_final.pdf
165 Sherlock WS(4) WS0000077333, para 4
166 Dame Jo Williams WS0000032071, para 31

Contact with the Trust

11.186 Dr Andrea Gordon became Regional Director of the CQC for the West and East Midlands, having previously worked for the HCC in that role. She visited the Trust a few times in the early months following publication of the HCC report and attended a meeting with Cure the NHS (CURE), also attended by Baroness Young.[167]

11.187 Following the HCC investigation in March 2009, a formal action plan was agreed between the Trust and the CQC that identified some 107 action points.[168] The CQC engaged with this process but were clear that they were not performance managers and that Monitor had overall responsibility for this, as they were the only organisation with statutory powers of intervention at the time.[169]

11.188 Dates were set to review the Trust's performance against the recommendations in the HCC report at the three, six and twelve month points. The CQC then undertook these planned reviews. Christine Braithwaite, then Head of CQC Investigations, identified 11 high level goals at her three-month review which were then narrowed down to five by Anthony Sumara when he took over as Chief Executive of the Trust.[170]

11.189 As part of the CQC's six-month review of the Trust, unannounced visits took place on 15 and 16 September 2009. On 17 and 18 September a total of 33 clinicians and staff were interviewed, as well as 20 patients and their relatives. Although progress had been made, the review identified unresolved issues in patient experience, clinical performance, leadership, governance, patient and public involvement, and staffing.[171] Further meetings between the CQC, Monitor and the Trust took place in October and November 2009, discussing the transformation programme for the Trust.[172]

11.190 Additionally, for the first year of the CQC's operation, the HCC's AHC was carried out for 2008/09 under transitional arrangements. The Trust provided a self-declaration against the core standards and the CQC took into consideration progress made against recommendations contained in the March 2009 HCC report.[173] The final AHC was published in October 2009. This was based on self-declarations from the Trust in May and October 2009 and assessed the Trust as "weak" for its quality of services and "good" for financial management. It was also assessed as non-compliant with 8 of the core standards it was assessed against.[174]

167 Gordon WS(2) WS0000040439, paras 11–12
168 Sherlock WS0000032376, paras 286–7
169 Sherlock WS0000032376, para 289
170 Sherlock WS0000032376, para 288
171 Sherlock WS0000032382, para 303
172 Sherlock WS0000032384, paras 307–308
173 Sherlock WS0000032367, para 260
174 Sherlock WS0000032367, para 260

11.191 Like all NHS providers at the time, the Trust also had to submit separately an application for registration under the 2008 Act in respect of HCAI between December 2008 and January 2009. To obtain registration the Trust had to complete an assessment and declare whether they met regulations for managing infection. As a result the Trust achieved full registration without conditions. The Trust was subject to three HCAI inspections, one under the HCC in October 2008 and two under the CQC in July and October 2009.[175] The result of these was that concerns were identified in relation to "ensuring that the environment for providing healthcare is suitable, clean and well maintained". However, a follow-up inspection in November 2009 confirmed that by this time the Trust had addressed this issue and that there were no outstanding areas for improvement.[176]

11.192 Under the Health and Social Care Act 2008, the Trust, alongside all NHS providers, was also required to submit its application for full registration with the CQC between 4 and 28 January 2010. This was submitted by the Trust on 7 January 2010 and the Trust declared itself non-compliant with five out of sixteen key outcomes, which were: (4) care and welfare of service users; (16) assessing and monitoring the quality of service provision; (11) safety, availability and suitability of equipment; (17) complaints; and (14) supporting workers.[177]

11.193 The CQC, on receiving the Trust's application, having also considered findings at the six- and twelve-month reviews, found that the Trust required six conditions on its registration, the additional non-compliant outcome not identified by the Trust being that of staffing.[178] At the time there was still an overall staff nursing deficit of 11%. The decision was communicated on 16 March 2010.[179] This conditional registration allowed the Trust to undertake four regulated activities at two sites.[180]

11.194 In September 2010 a planned 12-month review of the Trust took place, looking at all 16 outcomes assessed at registration, and on 29 October 2010 the report was published. The Trust was found to be complying with five of the sixteen standards, with minor concerns in relation to eight outcomes and moderate concerns in relation to three outcomes: (9) management of medicines; (14) supporting workers; and (17) complaints.[181]

11.195 The result of this was the issue of compliance actions by the CQC, requiring the Trust to submit action plans to state what action it was going to take to achieve compliance with these outcomes. At the end of November 2010 the Trust provided the CQC with a report to show how it would achieve and maintain compliance with outcomes 9, 14 and 17. However, review

175 Sherlock WS0000032373, para 276
176 Sherlock WS0000032373, paras 276–279
177 Sherlock WS0000032388, para 318
178 Gordon WS(2) WS0000040450, para 45
179 Sherlock WS0000032388, paras 319–320
180 Sherlock WS0000032388, para 321
181 Sherlock WS0000032388, para 331

of outcome 17 (complaints) was deferred in light of the recent high-profile death of twin babies following treatment at the hospital.[182]

11.196 The death of these baby twins led to an immediate meeting between the CQC and the Trust's Chief Executive Anthony Sumara. He was warned that he might want legal representation in the meeting and that evidence taken might be taken down and subsequently used. He was critical of the CQC in the way it treated the Trust and felt that the CQC acted in an extreme way when things went wrong at the hospital.[183] Dr Andrea Gordon, however, considered the CQC's response proportionate to the seriousness of the incident and stated she would have followed this up had it been any other trust.[184]

11.197 In November 2010, as a result of these deaths, a responsive review was carried out and a further review was conducted in January 2011 in order to follow up on compliance actions identified in September. At the January 2011 review the CQC felt good progress had been made by the Trust.[185]

Care Quality Commission organisation and culture

Introduction

11.198 The Inquiry benefited from considerable evidence about the CQC as an organisation that is highly relevant to the learning to be gained from the Stafford experience. The aspects of particular note were issues around:

- Strategy;
- Governance;
- Reaction to criticism and transparency.

11.199 The Inquiry's examination of the CQC needs to be considered in context. The organisation had only been established recently and was subject to the many obvious difficulties such an organisation is likely to face early on in its development. Throughout the period from 2009 to about April 2011 the CQC was preoccupied with setting up and implementing systems for registering and monitoring healthcare and adult social care providers, including 378 NHS trusts by April 2010, 24,000 adult social care providers by October 2010, and 9,000 dentists and ambulance providers by April 2011. The extent of this task should not be underestimated and in what follows that must be borne in mind.

182 Sherlock WS0000032392, paras 336–337
183 Sumara T58.59
184 Gordon WS(2) WS0000040454, paras 62–63
185 Sherlock WS0000032394, para 341

11.200 With regard to the CQC's culture, it has not been the primary task of this Inquiry to examine the culture of organisations after 2009. However, it is charged with ensuring that its recommendations can be applied to the system as it now is, and an understanding of current organisational culture is therefore important. What came to light in the course of the Inquiry evidence has been a cause of concern, as described below. While the instances mentioned may refer to the experiences of a limited number of people, the corporate responses to these individuals do suggest that attention is required to the general culture of the organisation if it is to be an effective regulator, and a role model to the healthcare system as a whole.

Strategy

11.201 The Inquiry heard evidence which raised questions about the ability of the CQC to develop and implement a strategy which worked at the front line.

Amanda Pollard's evidence

11.202 In July 2010 Amanda Pollard, who had considerable experience as an inspector of infection control and as a member of the CQC's HCAI team, wrote to Cynthia Bower to voice her concerns at the disbandment of that team and the focus on expediting registrations. Her anxiety had been raised by the experience of inspecting a PCT, detecting infection control concerns there, and the fear that disbandment of her team would lead to such matters not being detected in future by untrained, non-specialist inspectors. She was also concerned at the loss of expertise implied in the transfer of three specialists in infection control to general registration work. As she put it "No-one's going to die by not being registered."[186]

11.203 In her reply, Cynthia Bower explained that it had been decided to prioritise registration because it was a legislative requirement but also because it was an opportunity to assess all the evidence the CQC had on providers. She said that the early indications were that the registration process was a powerful tool towards improvement and she hoped that Ms Pollard would feel able to contribute her expertise not only in her inspections but to colleagues "through learning networks".[187]

11.204 In March 2011 Ms Pollard wrote again to Cynthia Bower to express her concerns. She moderated her tone because she did not want to prejudice her employment. She expressed concern that there was not sufficient time to undertake the number of planned inspections scheduled. She felt these were not achieving their intended purpose:

186 Pollard WS0000078118, paras 19–21; AP/3 WS0000078163
187 AP/3 WS0000078162

The public wants us out there seeing and experiencing what they feel – not stuck behind a desk writing 'table-top reports' that take up more time than getting into a car and spending a morning with a provider. Once we get over the threshold, we should assume that all will be perfect, and then focus on any triggers that DON'T meet the outcome/ standard bar ...[188]

11.205 She said her job felt like a "computer data inputter", rather than her previous role of thinking on her feet and being frequently on site.

11.206 In a short but positive reply Cynthia Bower said she agreed with much of what Ms Pollard had said and welcomed the fact that people like her were prepared to take time to think through what could be improved.[189]

11.207 From then on Ms Pollard's experience as an inspector was that a quota was imposed of 30 inspections a year, which was a challenging target. However, in what she regarded as a positive move that answered some of the concerns she had expressed in her email, the number of outcomes inspectors were expected to assess was reduced to five from the full range of sixteen core outcomes.[190] The number of planned inspections was also decreased, which she welcomed. However a new challenge arrived, she said, when the CQC undertook to the Parliamentary Health Select Committee in June 2011 that it would inspect all NHS and social care providers once a year.[191] She claimed there had been no consultation with staff about this change. According to her, this led to a number of undesirable consequences:

- Inspectors were told they had discretion in the number of outcomes they assessed, thereby leading to pressure to inspect for fewer, as the volume of inspections required had increased.
- Follow-up visits were discouraged by not being counted as an inspection and by the increased pressure of work.
- The quality of inspections was inevitably compromised.
- Desktop reviews were encouraged in preference to on-site inspections.
- Weekly team telephone meetings at which mutual issues were discussed had been abandoned. As all inspectors are now home workers. This has increased their professional isolation.

188 AP/8 WS0000078369
189 AP/8 WS0000078368
190 Pollard WS0000078126–127, paras 51–53
191 Pollard WS0000078127–132, paras 55–70

11.208 Ms Pollard concluded her statement to the Inquiry by saying that, based on her concerns, some of which have been summarised in this chapter:

> *In my view, those leading CQC are more concerned with how they and the organisation is presented in the press rather than listening to those working within the organisation. This is something to worry about. The organisation becomes dangerous when driven by reputation management, for example by promising to deliver annual inspections when this is simply not achievable; what suffers is the quality of the inspections. The culture driven by the leadership of the CQC is target-driven in order to maintain reputation, but at the expense of quality.*[192]

11.209 However she wanted to make clear:

> *I do believe that the CQC is making a difference to people's care. Unannounced on-site inspections are the way ahead. The CQC has inspectors well motivated to making that difference but we are doing that despite the lack of clear direction and support mechanisms not because of them.*[193]

11.210 While not all of them were accepted by the CQC, many of Ms Pollard's points appear to have been recognised in subsequent changes made by the CQC, which are summarised below.

Kay Sheldon's evidence

11.211 At the opposite end of the CQC's hierarchy, and entirely independently, the Inquiry was also approached after the formal conclusion of the oral hearings of evidence by Kay Sheldon OBE, a Commissioner since the beginning of the CQC and a former member of the MHAC. She gave extensive evidence of her concerns about the strategic direction and leadership of the organisation. Adopting the analysis of Counsel to the Inquiry, her views included the following:[194]

- There is no proper strategic approach by the CQC as to how it intends to regulate.
- There is no understanding at senior levels of the CQC as to what that its regulatory model should look like "on the ground".
- There is a lack of leadership on strategic issues.
- The organisation's approach is reactive and led by reputation management.
- The Board does not govern or lead the organisation in any real sense.
- Little consideration is given as to the capacity of the organisation to deliver what purports to be its strategy.

192 Pollard WS0000078138–139, para 93
193 Pollard T137.16
194 CL0000002431, *Counsel to the Inquiry's Closing Submissions*, Chapter 16 – The CQC, para 338

- Personal experience of inspections reveal that inspectors are inadequately trained for the roles they are given and inspections are consequently inadequate.
- In speaking to inspectors there is a sense of disenchantment and disharmony.

11.212 It is beyond the remit of this Inquiry to analyse the extent to which Ms Sheldon's concerns were in fact correct, but they were certainly worthy of consideration. At least some of what she raised appears to have been supported not only by the evidence of Ms Pollard and Ms Rona Bryce (a Senior Operations Analyst at the CQC), but also by contemporaneous documents, including a paper by members of middle management in October 2009.[195] Ms Sheldon had raised her concerns internally on a number of occasions, including in written communications to Board members in August and September 2011.[196] A strong challenge by her to a "strategy refresh" document in September resulted in an enquiry being made as to her health.[197]

Governance

11.213 There was also evidence suggesting that the leadership's view of how its strategy was working was not shared universally by front-line staff.

Amanda Pollard's evidence

11.214 Once it was decided to prioritise the registration process over compliance work because of the time limits that had been set, there is evidence that staff were placed under considerable pressure. In her registration work in the adult social care sector Ms Pollard felt there was considerable pressure for throughput of work and, she claims, staff were told that management would "name and shame" those not meeting their quota.[198] Ms Bower disputed that trusts were forced through without regard to safety issues and, she pointed out, trusts, including the Trust, were registered subject to conditions where it was considered appropriate.[199] However she accepted that this transitional position allowing trusts to be registered with conditions would change in the future, as new applicants now would not be granted registration in similar circumstances.[200]

11.215 Ms Pollard disputed, as indicated above, the claims made by senior management with regard to training inspectors. She felt uncomfortable in this role because of the lack of training and experience, but her perception was of a cultural expectation that staff should not be too open about lack of skills.[201]

195 CQC00000000427, *CQC and the Regulation of Social Care – Six Months On: A view from the middle of the organisation*; and CLO000002432-433, *Counsel to the Inquiry's Closing Submissions,* Chapter 16 – The CQC, para 341
196 KS/4 WS0000078551;
197 KS/14 WS0000078606
198 Pollard WS0000078119, para 25
199 Bower T87.19–21
200 Bower T87.20
201 Pollard WS0000078124–125, para 43

11.216 Ms Pollard felt that undue pressure was placed on her and colleagues to meet quotas: staff appraisals included criticism of teams falling short of the target, even where the individual had met his or hers. She claimed she was encouraged to put pressure on colleagues to ensure team figures improved. This led her to say:

> *The CQC is a blame organisation and the approach one is encouraged to take is to get your head down and not cause trouble.*[202]
>
> *We are made to feel guilty if we are not achieving one inspection a week and all of the focus is on speed, targets and quantity.*[203]

11.217 Her sense of anxiety was increased by her perception of the lack of training for inspectors on how to spot another case similar to Mid Staffordshire or Winterbourne View (see above).

11.218 Concerns were expressed about the accuracy of statements made by the CQC senior staff to Parliament and to the Inquiry. For example Ms Pollard questioned the accuracy of the statement made to the Health Select Committee that site visits are carried out on the basis of risk assessment.[204]

Rona Bryce's gap analysis

11.219 The Inquiry obtained evidence from Rona Bryce, Lauren Goodman (a CQC RIEO – Regional Intelligence and Evidence Officer), Sampana Banga (the CQC's Head of Operational Intelligence), and Richard Hamblin (the CQC's Director of Intelligence) following receipt of information from an anonymous source suggesting that the CQC had a document that might be of interest to the Inquiry. At an away day, Ms Bryce had been asked by Mr Banga, her manager, to prepare a report detailing all references in the evidence given by the CQC to the Inquiry that related to operations intelligence. There appears to have been a difference of understanding between Mr Banga and Ms Bryce about the purpose of the exercise, which is immaterial for present purposes. In undertaking this task, in addition to finding all the relevant references, Ms Bryce undertook a comparison between the evidence and what she understood to be the actual state of affairs on the ground. She consulted Lauren Goodman, and sent a draft to three colleagues. On 15 June she attended a meeting with Mr Banga and others about her work. She raised concerns about apparent inconsistencies between the evidence given to the Inquiry and what she and other perceived. She was advised that the CQC would address any inconsistencies in their closing submissions. The apparent inconsistencies which she had listed included:

- RIEOs were not routinely completing engagement forms in relation to local intelligence: this would mean that local intelligence might not be fully reflected in the QRPs;

202 Pollard WS0000078131, para 66
203 Pollard WS0000078132, para 68
204 Pollard WS0000078128, para 57

- Information from LINks was not being included in engagement forms;
- RIEOs did not routinely monitor the Customer Relationship Management (CRM) database and might therefore be unaware of information not included in the QRP;
- Notifications from the NPSA were not routinely reviewed by RIEOs;
- Inspectors' decisions on safeguarding alerts were not reviewed by RIEOs or Regional Intelligence and Evidence Managers (RIEMs) meaning there was no audit of the decisions to ensure consistency;
- RIEOs did not review inspectors' feedback on their actions in relation to alerts and would have been surprised to know they were expected to be doing this;
- RIEOs did not review governance structures;
- RIEOs are not alerted to a change in risk estimates.[205]

11.220 The document was discussed briefly with Mr Hamblin on 23 June 2011. Mr Hamblin disagreed with much of its content: he told the Inquiry that much of Ms Bryce's document was based on a misunderstanding of the evidence and did not reflect what the CQC actually did.[206] The CQC delivered a further rebuttal of the suggestions in this document in a letter of 19 August 2011.[207]

11.221 It would be disproportionate and unnecessary for the purposes of this Inquiry to undertake a forensic analysis of each issue raised by this evidence, but it is sufficient to conclude that at the very least the CQC's leadership was unaware of concerns among some at least of its intelligence officers about the accuracy of its understanding of how the CQC operated in practice. The analysis may principally have been the work of Ms Bryce, but it is clear that she had relevant knowledge, was acting honestly and constructively and took soundings from colleagues. For reasons that will be explored below, the CQC is not an organisation where staff are led to believe that criticism, however constructive, is welcomed, particularly when it is offered externally.

Kay Sheldon's evidence

11.222 Kay Sheldon's evidence has been in part addressed above. On the subject of governance, again adopting Counsel to the Inquiry's analysis, her concerns included the following:

- Challenges at Board level are sidestepped and not dealt with appropriately. Strategic decisions appropriate to be made at Board level are not made by the Board but by the executive with an expectation that those decisions will be approved. She referred to an occasion when the Board discovered a change of policy to introduce annual inspections from a media report.
- There is no proper debate about issues and Board decisions are neither made nor minuted. There was a consistent failure to chair meetings in a way that facilitated debate.

205 There are many drafts of this document but see RB/10 WS0000073856
206 Hamblin WS(2) WS0000074463, para 2
207 RB/13 WS0000073871

- There is a culture of bullying in the organisation, even at Board level.
- There is a lack of internal governance.
- The treatment of external stakeholders whose input is important has been poor and a number of stakeholders have been excluded without proper consultation or Board involvement.[208]

Transparency and the reaction to criticism

11.223 The CQC is required to be transparent in its activities. Section 83 of the 2008 Act requires it to produce an annual report. Its Board meetings and Board papers are public. Its regulatory reports are published.

11.224 Dame Jo Williams emphasised in her evidence that the CQC carries out its functions in an open and transparent manner.[209] Cynthia Bower demonstrated that she would reply personally to staff when suggestions were made, as exemplified by Ms Pollard's evidence about her email correspondence with her.

11.225 However the Inquiry received a concerning amount of evidence to suggest that the CQC is not an organisation that welcomes criticism offered internally, still less when it is expressed in public.

Evidence from staff survey

11.226 A staff survey conducted early on in the organisation's life suggested that only 18% of staff felt it was safe to challenge the way things were done.[210] Cynthia Bower's reaction was to take comfort from there having been similar results in other organisations going through change:

> *... of course, the staff survey wasn't a good survey. I'm not pretending that it was. But, again, in my experience it's not out of the ordinary for organisations that have gone through the sort of turmoil that CQC did, in order to bring it into existence, to have quite negative staff surveys so early on in their life.*[211]

11.227 She did not, however, agree that the evidence of Dr Wood and others (see below) to the Inquiry suggested that this view remained prevalent.[212] In a 2012 staff survey[213] 72% of respondents thought their line manager open to their ideas and suggestions and that this and

208 Sheldon WS0000078497, para 69; CLO000002431, *Counsel to the Inquiry's Closing Submissions*, Chapter 16 – The CQC, para 338
209 Dame Jo Williams WS0000032076, para 49; T84.153–155
210 *CQC slammed by own staff as survey exposes low morale* (8 July 2010), communitycare.co.uk, http://www.communitycare.co.uk/Articles/08/07/2010/114865/CQC-slammed-by-own-staff-as-survey-exposes-low-morale.htm; also quoted in AP/11 WS0000078461
211 Bower T87.105
212 Bower T87.105
213 *2012 Staff Survey Results for CQC Overall,* www.cqc.org.uk/sites/default/files/media/documents/cm031214e_item_17_annex_e_staff_survey_cqc_overall_scorecard_final.pdf

other positive results showed an improvement. This survey has not been evaluated by the Inquiry, but any organisation ought to be concerned if 28% of its staff did not think their line managers were open to ideas. In the same survey 66% disagreed with the suggestion that morale was good in the CQC, a minority of 43% had confidence in the decisions taken by their leaders, and only 18% agreed that changes were effectively implemented. Therefore there would appear to remain considerable room for improvement.

Experience of Ms Pollard

11.228 Ms Pollard gave evidence (see above) of a culture of having to keep one's head down. She was a persuasive witness because she demonstrated objectivity by willingly describing her earlier experience of receiving a positive reply from Ms Bower to her initial emailed suggestions.

"Non-disparagement" and "gagging" clauses

11.229 Some witnesses to the Inquiry who were former employees of the CQC required a direction to give evidence because of their fears about the effect of a clause in compromise agreements relating to the terms of their departure. Ms Bower told the Inquiry she had been advised that such terms were entirely standard. The Inquiry obtained copies of the CQC's standard clause as inserted in Dr Heather Wood's agreement:

> *That Dr Wood will not at any time hereafter make or repeat any statement which disparages or is intended to disparage the goodwill or reputation of the CQC, or any specified person and the CQC will use reasonable endeavours to ensure that no senior manager, tier 3 or above, with whom Dr Wood had direct dealings with her employment with the CQC, nor any specified person involved in the correspondence process surrounding the termination of Dr Wood's employment will make or repeat any statement which disparage or are intended to disparage the goodwill or reputation of Dr Wood.*[214]

11.230 Standing on its own, the clause would prevent any criticism or public comment on matters of public concern being made by Dr Wood of the actions of the CQC while she was an employee there, or even after she had left, if these would have an adverse effect on the CQC's reputation.

11.231 Ms Bower suggested the clause was subject to a "public interest override", but accepted that this was not made clear in the agreement.[215]

214 Bower T87.101; and OI00000000208 *Statutory Compromise Agreement between Heather Wood and the CQC, undated and unsigned*
215 Bower T87.103

11.232 The above clause did not apply to evidence given to the Inquiry because of the following additional provision:

> *The CQC confirm that it is not intended that any term of this agreement shall prevent and/or restrict Dr Wood in any way from attending and/or taking part fully, including giving evidence in any public inquiries connected to work which she carried out during her employment with the CQC.*[216]

11.233 However that provision has no effect on other forms of disclosure, short of a public inquiry. Even in that context, the experience has been that witnesses were concerned about the effect of coming forward and offering evidence. Therefore the agreement had a "chilling effect" inimical to the public interest and inconsistent with the role of the CQC as a regulator in a sector in which the public have a distinct right to know about concerns affecting their health and well-being.

Reaction to evidence of Ms Pollard and Ms Sheldon

11.234 The CQC's reaction to the decision of Ms Pollard and Ms Sheldon to give evidence was hostile.

- The week before they were scheduled to give evidence to the Inquiry, Dame Jo Williams sent a letter to all staff. In it she stated that:

 > *This* [the evidence] *could generate a lot of media coverage about us, this may be difficult, but we must not lose confidence in the great work we are doing and the huge progress we have made.*[217]

 She referred to the DH capability review that had just been announced and asserted that the DH had expressed recognition that the CQC had "really turned a corner as an organisation", citing support from the Secretary of State and the Prime Minister. Referring again to the new evidence:

 > *The kind of coverage we may get next week damages our reputation, damages our colleagues and weakens the future of the organisation … It is not in our interests, nor the public's who we seek to service, to have damaging accusations and personal opinions aired in the media, because a weaker CQC will find it harder to challenge poor care. Over the next few days we must be strong …*

- On the day they gave evidence, 28 November 2011, Cynthia Bower sent an email to all staff publicising positive achievements of the CQC, but urging staff to read a statement circulated in rebuttal of the evidence. She ended her email by stating:

216 Bower T87.103–104
217 CQC00000000590, *A letter to all staff from Dame Jo Willams, Chair* (25 November 2011)

I know there is more hard work to do and I know many of you feel angry that this is likely to be disrupted this week by witness evidence at the Mid Staffordshire Inquiry, but as we continue our work we should remember that CQC is in a different position – a very much stronger one – than it was just a year ago.[218]

- Three CQC commissioners circulated to staff a statement of support for the Chair, also made on 28 November.[219] In it they expressed disappointment at the views expressed by Ms Sheldon.

- A further statement was posted on the CQC intranet for staff which stated:

 ... while it is extremely disappointing that Kay Sheldon has chosen to raise her concerns in this way, the other members of the Board have made their support for our Chair, Chief Executive and our Executive Team absolutely clear. We welcome their support and that of other parts of the health and social care system[220]

 This referred to a statement posted from the chair of the staff forum emphasising that management had been open to receiving concerns from staff.[221]

- It has since become public that Dame Jo Williams wrote to the Secretary of State for Health on the day Ms Sheldon gave her evidence to the Inquiry, requesting him to remove Ms Sheldon from the CQC's Board.[222]

11.235 The concerns raised by Ms Sheldon and Ms Pollard appeared from the public response to them to be rejected out of hand by the CQC leadership, even though they were honestly offered, and apparently based on evidence. It is of note that those who have been charged by the DH with assessing the merit of those concerns appear to have accepted them in substance. The recent Performance and Capability Review by the DH came to conclusions which echoed many of the concerns Ms Sheldon in particular had expressed.[223]

11.236 The fact, if it be the case that other members of staff or Board members expressed concern at these disclosures and disagreed with them, is not itself a justification for responses to criticism evidencing such hostility. Disagreement has to be managed in any organisation, but rejection of views which are expressed in good faith and have substance is not the way to encourage a culture of openness, transparency and constructive debate.

218 CQC00000000592
219 CQC00000000594
220 CQC00000000596
221 CQC00000000599
222 *Exclusive: NHS watchdog claimed that whistleblower Kay Sheldon was 'mentally ill'* (15 August 2012), *The Independent*
223 A comparison between the conclusion of the DH review and the evidence of Ms Sheldon and Ms Pollard is at Appendix L

Reaction to disclosure of the work of Ms Bryce

11.237 The CQC's reaction to the disclosure to the Inquiry by an anonymous source of the comparison work undertaken by Rona Bryce between the evidence given on the CQC's behalf to the Inquiry and internal perceptions was also hostile.[224] Although there was no evidence that Ms Bryce was responsible for the information coming into the possession of the Inquiry – and she denied that she had been responsible for this – and a number of others had access to the information, she was threatened with suspension pending an investigation. She told the Inquiry that the meeting was "not a pleasant experience".[225] Although the threat was withdrawn, a clear message of disapproval was communicated to all, potentially causing considerable hesitation before anyone offered useful information to the Inquiry.

11.238 Senior CQC witnesses made it clear in their evidence on this matter that if they had believed that discrepancies had come to light, they would have informed the Inquiry about them. However, the outright rejection of the suggestion that there had been such discrepancies suggests that they probably would not have disclosed the concerns raised by the Bryce analysis to the Inquiry, even after a completion of a senior level review of it.

Conclusions

Independence of the Care Quality Commission

11.239 The CQC has a structurally close relationship with the DH and the Government. The DH is in a position to dictate not only the appointment of commissioners, but also direct action by the CQC. It can influence its activities by dictating the standards to be applied, and the extent of the resources allocated to it.

11.240 The DH is also an interested party in relation to the CQC's assessment of NHS trusts, and Ministers will be politically accountable – in practice, even when not in theory – for reports disclosing serious failures. The Inquiry has seen no evidence from which it would be proper to conclude that the proximity of the relationship resulted in improper pressure or influence being brought to bear on the CQC or its leadership, although on her own admission it was not a relationship the first Chair of the CQC found it possible personally to manage.

11.241 The CQC has the function of upholding standards for the purpose of protecting patients and enforcing them, if necessary by criminal prosecution. While it may be impractical to separate it entirely as an organisation from the DH, it needs to be seen to be acting entirely independently. It should only be in the most extreme circumstances that the Government considers it necessary to intervene.

224 See above for more detailed account
225 Bryce WS0000073812–813, para 79; and Bryce WS(2) WS0000078643–644, paras 2–3

11.242 In fact, the interventions that have taken place have on the whole appeared positive:

- It appears that the inspections that have been required by the Secretary of State, for example the Dignity and Nutrition Inspections, have revealed widespread cause for concern and have prompted action designed to improve standards to an acceptable minimum.[226] It is not clear that these concerns would have been brought to light so rapidly by the CQC's routine procedures.
- The DH Performance and Capability Review reflected many of the concerns voiced in this Inquiry.
- A commissioner appears to have been saved from dismissal when the grounds for such action were thought to be absent.

11.243 Therefore it may be that the CQC is not yet of a sufficient maturity for a more complete autonomy to be considered, but such a step should be kept under review. What is required, however, is a meticulous transparency in the dealings between the DH and the CQC. Where issues relating to regulatory action are discussed, it is important that these are properly recorded so that no suggestion can be made that inappropriate interference in the CQC's statutory role has occurred.

11.244 Another way in which the autonomy of the regulatory system as a whole could be protected is by the transfer of the power to define guidance and standards to NICE or some similar body, while retaining for the Secretary of State the power to define unacceptable outcomes (see the standards section below).

Initial registration

11.245 The initial registration of NHS trusts and foundation trusts (FTs) seems to have been influenced by time pressures not of the CQC's making. The process has echoes of the change in emphasis in foundation trust policy (which broadened applicants beyond those with three stars), in that regulatory requirements had to be tailored to a policy change. In this case, a high proportion of trusts declared non-compliance, or raised concerns about compliance, with some of the new outcome-based standards. Yet only a small handful, including, not surprisingly, the Trust, were made subject to conditions. Pragmatically, it would have been a disaster if all existing NHS trusts and FTs had not been registered. It might have been simpler to allow them registration by default and then to have focused on taking regulatory action as necessary to bring about compliance with the new standards. This would have had the benefit of freeing up CQC resources for focused compliance regulation.

11.246 The criteria for registration of new applicants have been strengthened so that after 2010 only applicants who were fully compliant were granted this status.

226 Bower T87.54–5

Strategic direction

11.247 The general theory of the new regulatory model is encouraging: it depends on the collection of a wide range of information, which is used to identify a level of risk of non-compliance, which in turn informs decisions on which organisations to target for review.

11.248 However, the CQC has had many challenges since its inception, including the need to merge three organisations, the creation and administration of an entirely new system of registration, and the monitoring of compliance with a new set of standards. Added to these challenges has been the requirement to take on the regulation of other healthcare sectors. All this has had to be achieved within a short timescale. There can be no one correct way to have set about this task and it was inevitable that changes of strategic direction will have been necessary to react to growing experience. The evidence does, however, give the impression that strategy has, to some extent, been driven by a perceived need to fit the very wide range of activity required of the organisation to the resources available.

11.249 These pressures have, perhaps predictably, led to it being less than easy to fulfil the basic tasks that the CQC is charged with, namely protecting patients from sub-standard care and the provision of accurate information on which the public and others can rely to make decisions. If, as has been suggested by some witnesses, there has been a lack of strategic direction, then this needs to be rectified as a matter of urgency. At the very least, there is a requirement for the leadership to communicate to its staff, with a degree of clarity that may have been missing to date, what that direction is in a manner calculated to attract their confidence and commitment to the continuing and important task. Whatever cause for dissatisfaction there may be, the temptation to abolish this organisation and create a new one must be resisted. If change is required, it should be by evolution, but not evolution that proceeds at a glacial rate. Proper and achievable strategic goals need to be set and progress towards them monitored. The CQC's central task of ensuring the application of acceptable standards by registered providers is too important to abandon, and yet another major upheaval is to be avoided if possible. The experience of the creation of the CQC demonstrates how fraught and distracting a process that can be.

11.250 The CQC has accepted, following the various reviews of its performance that have taken place since the oral hearings, that its strategy has to be constrained by its operational activities. Since the oral hearings there have, in addition to the reviews by other agencies mentioned in this chapter, been a number of strategically related developments. While these have not been evaluated by the Inquiry, it is possible they go towards addressing the concerns raised in the evidence. In particular the Inquiry has been informed that:

- The CQC has agreed in its response to the DH Performance and Capability Review that it was essential that its strategy was reviewed. A new strategy is being developed aimed at producing different regulation methods for different sectors based on an evaluation of

what best drives improvement. It is intended that the focus now should be on identifying areas of non-compliance rather than compliance;
- Steps have been taken to improve staff relations via the staff forum;
- A unitary board structure under which the Chief Executive is a member of the Board has been adopted;
- Additional non-executive directors are being appointed;
- A formal corporate governance framework is being introduced which will meet monthly;
- Non-executive directors are challenging more than previously and there is said to be a clearer understanding of the role of the Board.

Care Quality Commission culture

11.251 The evidence received by this Inquiry does not suggest that the CQC is a happy environment to work in. The massive upheaval that has taken place in its creation has led to some elements of staff, from the front line to the Board, to express concerns and to believe they have not received an adequate response. While it is clear that the CQC aspires to be an organisation that welcomes constructive comment, for example through staff surveys, the Inquiry has seen evidence of a defensive institutional instinct to attack those who criticise it, however honestly and reasonably expressed those criticisms may be. The tendency shown has been to reject the message through the circulation of emotionally charged responses to staff. One witness to this Inquiry has been threatened with suspension, and an attempt has been made to have another dismissed. Clauses have been inserted into termination agreements seeking to restrict the freedom of speech of former employees. While it is necessary to be alert to the risk of extrapolating from isolated incidents, the evidence presented to the Inquiry shows a pattern consistent with a negative and closed culture of the sort the CQC should be combatting rather than, however unintentionally, exemplifying. A healthcare regulator needs to be a model of openness and therefore to welcome constructive criticism. If it seeks, as it should, to encourage employees in regulated organisations to come forward with concerns, it must be prepared to accept approaches made by its own staff in good faith to other agencies, including inquiries such as this one. It can only foster a healthy, open and honest culture within the healthcare system if it does so within its own organisation.

11.252 The Inquiry has been informed since the oral hearings that the CQC no longer intends to use "non-disparagement" clauses in termination agreements, unless there are exceptional circumstances.

Setting standards

11.253 The current structure of standards, laid down in regulation, interpreted by categorisation and development in guidance, and measured by the judgement of a regulator, is clearly better than what has gone before, but it requires improvement.

11.254 A tremendous amount of work has obviously gone into matching the outcomes in the essential standards with the regulations. However, there is a lack of clarity in the regulations, which the CQC is obliged to work under. They combine in one regulatory requirement a number of different concepts, such as "safety" and "welfare".

11.255 Both the regulations and the standards express completely acceptable requirements in very general terms, and the guidance suggests, in very high-level terms, the type of evidence that might prove compliance. What is more difficult to find is specific guidance that might enable clinicians, managers or providers' boards to achieve the standards. The balance between a level of prescription which constrains innovation and a lack of detail which allows an unacceptable level of variation is difficult to strike.

11.256 The regulations are intended to prescribe conditions which it is a criminal offence not to meet. The approach taken is not dissimilar to that adopted under the Health and Safety at Work Act 1974, where broad-ranging offences are created, many based on requirements of reasonableness and judgement, underpinned by more specific codes of practice, leaving a wide discretion to regulators as to what should or should not be prosecuted. Therefore the CQC has to approach the issue of prosecution with great caution, as is apparent from its guidance, only prosecuting in the clearest of cases, and only following non-cooperation on the part of the provider. It is therefore very unclear what is regarded as serious and what is not.

11.257 In the healthcare field, these features mean that the standards, the regulations and the outcomes represented are likely to be "owned" by the regulators rather than clinicians or providers' managers. They will remain regarded as bureaucratic measures which have to be met formally by the production of relevant "evidence" when this is required. They are requirements which are to be met, but not necessarily paid very much attention to, in day-to-day clinical work. A nurse is unlikely to think about her employer's compliance with, for example, outcome 4 while considering a care plan for a patient, yet in theory, at least, she could be causing her employer to commit a criminal offence by her actions or inaction.

11.258 Unfortunately, for all the good intentions and improvements on what went before, the structure under which the CQC is required to work is over-bureaucratic and does not separate clearly what is absolutely essential from what is merely desirable.

11.259 While it is acceptable for high-level standards to be set in regulation and reviewed by Government, the underlying expectations should be set using a professionally informed and evidence-based methodology exercised by an independent clinically driven body. One such body already exists: NICE. It has a proven track record of producing evidence-based standards which are largely accepted by practitioners and of taking proper account of economic considerations.

11.260 If standards for healthcare are to be meaningful it is suggested that several ingredients are required.

A clear set of outcomes which are unacceptable, defined by regulation as fundamental standards

11.261 These might be matters which are universally regarded as unacceptable on safety grounds, or fundamental requirements of quality. For example:

- It is unacceptable for a patient to be injured in the course of treatment by a failure without reasonable excuse to provide prescribed medications;
- It is unacceptable for a patient to be injured by contracting certain types of infection as a result of the failure to apply methods of hygiene and infection control accepted by a specified standard-setting body, peferably NICE;
- It is unacceptable for treatment to be given to a patient without his or her informed consent or other lawful authority;
- It is unacceptable for a patient to be left without the nutrition and hydration reasonably required by a patient in his or her condition, or any necessary assistance to consume such nutrition and hydration;
- It is unacceptable for a patient to be discharged from hospital without adequate notice for arrangements to be made for the provision of any continuous care or support required.

11.262 It should be an offence for death or serious injury to be caused to a patient by a breach of these regulatory requirements, or, in any other case of breach, where a warning notice in respect of the breach has been served and the notice has not been complied with. It should be a defence for the provider to prove that all reasonable practicable steps have been taken to prevent a breach, including having in place a prescribed system to prevent such a breach.

11.263 *A duty to maintain and operate an effective and safe system defined by regulation* that avoids unacceptable outcomes or, where elimination of the risk of the outcome is not reasonably practicable, reduces the risk to a practicable minimum. For example:

- A system that ensures consent or other lawful authority is obtained for all treatment. As giving treatment without consent is unlawful, it is reasonable to require the system to be infallible, as redress for the patient and sanctions should follow automatically;
- A system that reduces the risk of unavoidable iatrogenic injury to patients to a minimum. It has to be accepted that not all individual errors can be eliminated by systems, but proper clinical governance will reduce the risks;
- A system of hygiene and infection control that maintains in operation a specified methodology;
- A system of ensuring that adequate facilities and staff are in place to ensure the necessary nutrition and hydration is provided to patients.

Standard procedures and practices for complying with the duties and avoiding the proscribed outcomes

11.264 NICE has been tasked with producing Quality Standards for individual procedures and areas of treatment and these should be extended as soon as possible. Organisations need a means of being advised on best practice in each area, and to be given strong and practical guidance on what can be done and how it can be achieved and measured. How the duties are fulfilled may vary from speciality to speciality. While it would not be compulsory to comply with such procedures and practices, an organisation could be required to prove that it had an equally safe equivalent in place. Such procedures could be the subject of formal adoption by the regulator after being proposed by a recognised external body.

11.265 NICE Quality Standards currently define a level of best practice, and it is intended that these should be incorporated into the commissioning framework. At the moment each Standard consists of a "Quality Statement", which identifies "key markers" of "high quality and cost effective care" for a particular condition or pathway, and a "Quality Measure", which provides a means of and a process for measuring compliance. Examples of NICE standards, taken from the standard for dementia care (as set out at Annex M), show how it is able to distinguish between standards requiring invariable compliance and those which are less rigorous. The measures devised for dementia standards have already proved their worth through the results of the first National Audit which demonstrated the gap between hospitals' policies and what went on in practice.

11.266 Standard procedures using this methodology could define a minimum acceptable level of precaution to be taken with regard to complying with the regulatory fundamental standards. While standards could also offer ways of achieving a higher than minimum quality, it would only be the fundamental level which would be the subject of regulation. The more such fundamental safety standards were created in this way, the greater clarity would exist around what constituted the fundamental requirements of safe treatment to adequately meet patients' needs.

11.267 In the absence of a NICE Quality Standard, reference could be made to guidance produced by or on behalf of Royal Colleges or recognised specialist groups. For example if the Royal College of Surgeons produced a standard operating theatre protocol for a certain type of surgery, this could be adopted by the regulator. The Royal College of Psychiatrists in collaboration with other bodies produced the detail of the criteria lying behind the measurement of the NICE dementia standard.

11.268 Ideally there should be a recognised system for the review of proposed standard procedures managed or supervised by NICE. In addition to producing its own procedures by its normal methods, it could evaluate and approve, possibly provisionally, procedures proposed by other bodies.

11.269 Compliance with standards and guidance produced which focus on fundamental requirements a breach of which is unacceptable, should be policed by the CQC. In this way the regulatory system would be reinforced by methods and measures identified by professionals and based on clinical experience and the interests of patients. It would be the duty of the regulator to enforce a clear fundamental set of standards, driven by the interests of patients, and devised by clinicians, a "bottom up" as opposed to a "top down" system. Where injury or death results from a failure to meet these fundamental standards, criminal sanctions would be available to be policed by the CQC.

11.270 Standards which required a higher level of attainment would be a matter for the commissioners through agreements with providers, to apply and enforce.

Standards for staffing

11.271 As a matter of priority, the guidance referred to above should include what each service is likely to require as fundamental in terms of staff numbers and skill mix. This should include nursing staff on wards, as well as clinical staff. The evidence suggests that the guidance is not readily available and that it is considered difficult to produce standards. Authoritative guidance in this field is urgently needed for a number of reasons:

- The experience of Stafford shows that in times of financial stringency, expenditure on staff is vulnerable and cuts in staff are comparatively easy to make.
- Without guidance on numbers and the competency and skill mix, it is difficult for boards to judge the likely impact of staff reduction proposals.
- While it should not have taken the executive at the Trust as long as it did to complete a skill mix review, it is likely that other boards would face similar difficulties if faced with concerns about staff. More and specific guidance will assist in facilitating such reviews.
- Terms of authorisation and no doubt commissioning arrangements include obligations to have an adequate staff, but no means appear to be available to measure this. The CQC currently looks at outcomes on the ward and then, if those cause concern, at staffing. This runs the risk of detecting a problem after patients have suffered, not before. The problem is not just one for the regulator but for providers' boards as well.

11.272 It is already possible at ward level to establish the staffing needs for individual patients or a collection of patients in most cases – otherwise it would not be possible to organise effective rotas. Clearly there are difficulties in anticipating precisely the needs of patients collectively, and any guidance will require flexibility and due regard to the needs of different specialties and limitations on resources. For this reason it would be appropriate for the guidance to be created by NICE after appropriate input from specialities, professional organisations, patient and public representatives, and consideration of the benefits and value for money of possible staff to patient ratios.

Clinical governance standards.

11.273 There are currently no clear, separately identified standards for clinical governance systems, although some elements of governance are included in the essential standards. The CQC considers that these cumulatively require an effective governance system to be in place. While a return to a focus on systems rather than outcomes would not be welcome, as can be seen from the story of Stafford, boards cannot fulfil their duties without a proper and working system. There may be no one model of governance that is better than others, but the ingredients are probably relatively easy to identify. All the required elements of governance should be brought together into one comprehensive standard. This should require evidence not just of a working system but should demonstrate that it is being used to good effect. This should assist the CQC in the task of establishing the extent to which a trust's non-compliance is incidental or systemic, and trust directors to better understand what it is their responsibility to have in place. Any example of a serious incident or avoidable harm which comes to the attention of the CQC should trigger an examination of how that was addressed in the governance system and in particular a requirement that the trust concerned can demonstrate that the learning to be derived has been successfully implemented. While the CQC does currently look at governance structures if it has concerns in this regard,[227] a distinct standard would allow it in a more systematic and transparent manner to distinguish between the governance regimes required by different types of organisations.

Methods of monitoring compliance

11.274 The sense to be gained from the evidence before the Inquiry is that there has been a change of direction from an emphasis on planned, routine reviews, to more focused responsive reviews triggered by concerns. In addition, a substantial series of inspections has been carried out at the direction of the Secretary of State. It is clear on the other hand that the CQC intends to maximise the ability to make decisions based on a comprehensive database of risk information relevant to the assessment of risk.

11.275 Information of the type being introduced to the QRP is invaluable, although it is important that greater attention is paid to the narrative contained in, for instance, complaints data, as well as to the numbers. This system is admittedly in the process of development, but it is clear that the QRP is a significant improvement on what went before.

11.276 Information, however impressively collected and analysed, is not sufficient. It should not result in a reduction of the active consideration of the compliance in each provider. This is something that can only be undertaken in a manner commanding the confidence of the public and bringing home the importance of compliance by means of physical visits to premises, interaction with service users and staff, and the inspection of records. The experience of Stafford and of the HCC's AHC approach has demonstrated the insufficiency of over-reliance on

227 Sherlock WS0000032354, para 212

self-declaration and examination of policies. Therefore, it is necessary to maintain and develop an emphasis on inspection as the main method of monitoring compliance.

11.277 There was much debate about the merit of a central investigation team. Its attraction was that it was a centre of expertise and authority able to undertake in-depth inquiries. It was the resource in the system that finally drew attention to Stafford. The activity of Dr Heather Wood and her team demonstrated conclusively what can be achieved by in-depth, expertly and persistently handled inspection. However, it is not the only way in which expertise can be provided for inspections, and given the number of regulated bodies to be considered, some other source of expertise would in any event be required. Therefore there is nothing intrinsically wrong with an approach that relies on a system of local inspectors who build up local knowledge and experience. The problem of "regulatory capture" has been raised, but it is probably overstated. As long as those who supervise inspectors are aware of the possibility, it can be addressed as an issue.

11.278 The need for risk-based reviews or inspections is recognised by the CQC and it appears that an increasing amount of inspectors' time is taken up with them. That inevitably causes a challenge in relation to the performance of planned or routine reviews of organisations which have not shown an increased level of risk on the QRP. The change of policy to expect planned reviews to take place annually may not be easy to implement, given the constraints of resources. The story of Stafford shows the importance of not ignoring trusts that have failed to appear on the radar of concern.

11.279 No system of information gathering and analysis is perfect or sufficiently sensitive to pick up all problem trusts. Therefore routine monitoring, as opposed to acceptance of self-declarations of compliance, is essential. However, the CQC should consider whether it can enhance the assistance it obtains in this sort of review from:

- Reference to the QRP;
- Review of quality accounts, if they were externally audited and contained evidence of confirmation of compliance or non-compliance with relevant outcomes or standards;
- A report from Local Healthwatch;
- An enhanced system of peer review, which is recommended in *Chapter 21: Values and standards*. What is essentially required for trusts not currently known to be a cause for concern, is a means of professional monitoring more likely to detect problems, rather than a paper-based remote exercise;
- Themed inspections.

11.280 The more monitoring of this nature is effective, the less the need for the Secretary of State to direct ad hoc series of inspections.

11.281 The use of "generic" inspectors, who are expected to monitor all forms of registered organisation, is a matter of concern. The needs of an inspector of a small home for the elderly and a large NHS teaching hospital are very different. Both require training and a degree of specialist knowledge, without which there is a danger of missing important indicators of potential non-compliance. It is suggested that for providers of hospital care, a specialist cadre of inspectors should be developed by thorough training in the principles of hospital care. Inspections should be led by such inspectors, who should have the support of a team including service user representatives, clinicians and any other specialism necessary because of particular concerns. This Inquiry has not considered in any depth the issue of the independent sector, but as the standards must be the same there may be no reason why a hospital inspection team could not cover the independent sector as well as the NHS.

11.282 At the Inquiry seminars, other models of inspection were examined, including Her Majesty's Inspector of Prisons (HMIP). While there are fewer establishments for this inspector to look at, it was notable that he is able to undertake swift and effective inspections, often carried out on a themed basis, and produce clear and informative reports on the institutions visited. As was noted with the HCC reports, it may be that HMIP's reports are written in more dramatic language than the CQC's because he has no regulatory powers of intervention. However, it is not the style of the report that matters but the ability of an inspector to root out evidence of non-compliance with standards, which cannot be found merely by looking at a paper trail.

11.283 There is no reason why a CQC inspection cannot be conducted in collaboration with other agencies, or take advantage of any peer review arrangements available. Elsewhere in this report, the contribution to be made by a more extensive peer review system is considered.

11.284 Since the oral hearings and the seminars the CQC has informed the Inquiry that it has introduced at a national level a number of steps designed to improve the standard of its judgement. In summary these have included:

- Additional training for inspectors;
- Peer review processes;
- National quality panels to review evidence and compliance judgements to ensure consistency;
- A national operations risk and compliance group to consider complex cases and a regulatory risk committee to replace the risk and escalation committee;
- Quality assurance tools, which have been reviewed, updated and introduced;
- Enhanced management assurance tools, which have been introduced, and on which it is intended to undertake further development;
- Regional risk panels, at regional level, more readily accessible enforcement and legal advice and quality, risk and assurance managers which have been introduced;

- About 300 "experts by experience" which the Inquiry has been informed that the CQC now has who have been used in 470 inspections between April and July 2012;
- A new bank of professional advisers consisting currently of 172 currently practising professionals from backgrounds including nursing, midwifery, hospital practice, general practice, dentistry, social care and management;
- Revised guidance issued to inspectors on how to work with experts and professional advisers.[228] This states that "inspections are usually carried out by one inspector but for some inspections you may decide to get extra help". A compliance manager has to agree to the use of additional inspectors or experts in inspections;[229]

The CQC has also informed the Inquiry that it intends to continue to invest in training of inspectors.

11.285 There is little doubt that the CQC has modified its approach to monitoring and enforcing compliance. In a document published in April 2012 the CQC announced that following a consultation it intended to:

- Have a process which is more streamlined and responsive, to continue to keep the experiences people have when receiving care and the impact it has on their health and well-being at the centre of their work;
- Conduct more frequent inspections, of more services, including an inspection of most hospitals at least once a year and re-inspection of those failing to meet essential standards, and inspections at any time if concerns about poor care are raised;
- Target inspections more by focusing on a smaller number of standards, a minimum of one for each of the five domains, taking account of the type of care provided and the information held on it.[230]

11.286 It has not been possible to evaluate these changes or the extent to which they reflect the need for effective inspection as outlined above. Therefore the process adopted now by the CQC should be reviewed as a whole to ensure that it is capable of delivering regulatory oversight and enforcement effectively in accordance with the principles outlined.

The patient voice

11.287 While the CQC is to be commended for its efforts in this regard, in particular through its "experts by experience" scheme, the impression is that patient information and feedback is not a priority as a means to obtaining relevant information about an organisation or generally when the CQC is considering its regulatory approach. There seems to have been a lack of contact with Cure the NHS, for example. It is service users, including visitors and families, who are likely to be the first to witness poor outcomes or the warning signs that standards are

228 *Inspector's Handbook – Compliance inspections* (July 2012) CQC
229 *Inspector's Handbook – Compliance inspections* (July 2012) CQC, paras 3.7.2, 3.7.5
230 *Improving the way we regulate* (April 2012), CQC

slipping. It is here that a more specific focus by local inspectors on complaints, allowing perhaps for contact with complainants, would be of great assistance.

Supervision of the Trust

11.288 The description given above shows that the CQC has undertaken intensive scrutiny of the Trust since the HCC report. This has not been unequivocally welcomed by the Trust leadership. Antony Sumara, former Chief Executive of the Trust, told the Inquiry:

> *... because of the Francis report and because of this public scrutiny,* [the level of scrutiny of the Trust] *has gone up several notches in terms of ... the threshold they apply to Mid Staffordshire ... now, apart from I don't like the approach* [of the CQC to an incident at the Trust regarding the death of two babies] *and I understand how serious an issue like that is, that sort of approach will get you what we've got in the NHS at the moment, which is people saying "I haven't got any problems. Don't come anywhere near here."*[231]

11.289 Manjit Obhrai, former Medical Director at the Trust, described how the CQC had carried out a responsive review in relation to a serious incident concerning use of medicines, only six weeks after it had carried out a formal review, and found similar areas of non-compliance in each:

> *My issue was how much can you change in six weeks? ... We have engaged with the CQC fully every single time they've come, but the disruption that it causes.*
>
> *I think the ... thing for me is that the damage it does to the organisation in terms of individuals working in the organisation, if I was a surgeon or a physician working here, and I've got the option of working here or in an adjoining trust, where they don't have the level of scrutiny, where would I choose to work? Where would I work as a member of the nursing staff? You know, what is level of scrutiny that is appropriate, and what is inappropriate?*[232]

11.290 However, it is inevitable that after a failure of the magnitude uncovered by the HCC, the Trust was not going to be treated as a normal healthcare organisation until it had proved it had returned to an acceptable standard in all respects. While it may be thought to be unfortunate that some matters are being dealt with more seriously than they would otherwise have been, this may be a sad testimony to the tendency of the NHS to tolerate what is unacceptable in so far as patients and their families are concerned.

231 Sumara T58.98-9
232 Obhrai T55.176

11.291 In spite of what some in the system might regard as administrative inconvenience, after a failure of this gravity a healthcare organisation in the position of the Trust and its regulators should proceed on the basis that it has an even greater duty than before to satisfy the public that it is complying with minimum standards. It appears that the CQC has, within the limitations of its regulatory system, been determined to adopt such an approach. Such an approach cannot however be a model of how all organisations should be regulated. The intensity of scrutiny not only hinders the efficient management of a fully compliant trust but is an unsustainable drain on the resources both of the trust and the regulator.

Would the current system detect another Stafford?

11.292 While it is claimed that the lessons from the Mid Staffordshire NHS Foundation Trust are at the centre of the CQC's thinking, there has not to date been any formal external stress-testing of their current systems against what is now known about the Trust.[233] Dame Jo Williams told the Inquiry that the CQC had undertaken several reviews looking at various aspects of how they go about their business, but accepted there was no reason why the CQC should not specifically consider whether its process would now detect the issues of the type that existed at the Trust earlier than had been the case.[234] The CQC was, she said, considering an external evaluation of its impact on healthcare services.[235] This, the Inquiry has been informed, has now been commissioned and was due to report in December 2012.

11.293 Dame Jo said she would like to think that the issues at the Trust would have been detected earlier by the CQC's processes. She referred to its more sophisticated use of data and evidence, the recognition of the centrality to their understanding of the service users, the importance accorded to whistleblowers, and more effective working relationships with Monitor and other agencies. She considered that the use of local staff meant that the organisation had better local intelligence.[236]

11.294 Cynthia Bower expressed confidence that the issues would have been uncovered by the CQC's methods, and she pointed to more sophisticated use of the mortality alerts and listening to the patient voice as the means by which this would have happened.[237] While it is true that this might have led the CQC to a quicker conclusion than the process that would have been followed by the HCC, as the CQC would not have undertaken a full-blown investigation, it is not sufficient to be content with this. By the time mortality outliers appear it may already be too late to prevent the suffering and possible deaths of a significant number of patients. One of the issues at the Trust was that the patient voice was not expressed with any volume until late in the day for the reasons that have been examined.

233 Bower T87.45
234 Dame Jo Williams T84.171–172
235 Dame Jo Williams T84.103
236 Dame Jo Williams T84.173–174
237 Bower T87.120–121

11.295 Any regulatory system needs to have highly sensitive indicators of non-compliance and then act with rigour to prevent matters deteriorating or continuing. This requires alertness, for example, to serious complaints and incidents, or other causes for concern, and a refusal to tolerate them, rather than waiting for an accumulation of similar evidence. Cynthia Bower herself pointed out the NHS, unlike the private sector, is full of means for a trust to say it is taking action about something. These claims can be, and have been, seductive, but the role of the regulator is not to tolerate a lapse in minimum standards. There must be a continuing search for ways of identifying an increasing range of early warnings signs.

11.296 There are encouraging signs that the CQC is now changing the emphasis of its approach to a more assertive one, although it has not been possible to evaluate many of the steps taken in that direction as they have been put in place recently.

11.297 The CQC should therefore undertake a formal evaluation of how it would detect and take action on the warning signs and other events giving cause for concern at the Trust as described in this report and the report of the first inquiry and open that evaluation for public scrutiny. Although the problems at the Trust appear now to be historic in nature, they provide a useful example of a series of warning signs, which could occur again in the future. Thus the exercise is clearly worthwhile.

Other recommended improvements

Constitution

11.298 While it is right that the CQC's Board should continue to have a majority of lay members, the CQC could benefit from a closer involvement of the healthcare professional community.

The Care Quality Commission and provider development

11.299 The role of the CQC should be strictly confined to the regulation of fundamental acceptable standards of safety and quality. Developmental or aspirational standards should be a matter for commissioners to incentivise or specify. The regulator should focus exclusively on what is required to protect patients from avoidable harm or standards of care and treatment which are otherwise unacceptable.

Summary of recommendations

Recommendation 15

All the required elements of governance should be brought together into one comprehensive standard. This should require not only evidence of a working system but also a demonstration that it is being used to good effect.

Recommendation 37

Trust Boards should provide, through quality accounts, and in a nationally consistent format, full and accurate information about their compliance with each standard which applies to them. To the extent that it is not practical in a written report to set out detail, this should be made available via each trust's website. Reports should no longer be confined to reports on achievements as opposed to a fair representation of areas where compliance has not been achieved. A full account should be given as to the methods used to produce the information.

To make or be party to a wilfully or recklessly false statement as to compliance with safety or essential standards in the required quality account should be made a criminal offence.

Recommendation 38

The Care Quality Commission should ensure as a matter of urgency that it has reliable access to all useful complaints information relevant to assessment of compliance with fundamental standards, and should actively seek this information out, probably via its local relationship managers. Any bureaucratic or legal obstacles to this should be removed.

Recommendation 39

The Care Quality Commission should introduce a mandated return from providers about patterns of complaints, how they were dealt with and outcomes.

Recommendation 40

It is important that greater attention is paid to the narrative contained in, for instance, complaints data, as well as to the numbers.

Recommendation 41

The Care Quality Commission should have a clear responsibility to review decisions not to comply with patient safety alerts and to oversee the effectiveness of any action required to implement them. Information-sharing with the Care Quality Commission regarding patient safety alerts should continue following the transfer of the National Patient Safety Agency's functions in June 2012 to the NHS Commissioning Board.

Recommendation 42

Strategic Health Authorities/their successors should, as a matter of routine, share information on serious untoward incidents with the Care Quality Commission.

Recommendation 44

Any example of a serious incident or avoidable harm should trigger an examination by the Care Quality Commission of how that was addressed by the provider and a requirement for the trust concerned to demonstrate that the learning to be derived has been successfully implemented.

Recommendation 45

The Care Quality Commission should be notified directly of upcoming healthcare-related inquests, either by trusts or perhaps more usefully by coroners.

Recommendation 46

The Quality and Risk Profile should not be regarded as a potential substitute for active regulatory oversight by inspectors. It is important that this is explained carefully and clearly as and when the public are given access to the information.

Recommendation 47

The Care Quality Commission should expand its work with overview and scrutiny committees and foundation trust governors as a valuable information resource. For example, it should further develop its current 'sounding board events'.

Recommendation 48

The Care Quality Commission should send a personal letter, via each registered body, to each foundation trust governor on appointment, inviting them to submit relevant information about any concerns to the Care Quality Commission.

Recommendation 49

Routine and risk-related monitoring, as opposed to acceptance of self-declarations of compliance, is essential. The Care Quality Commission should consider its monitoring in relation to the value to be obtained from:

- The Quality and Risk Profile;
- Quality Accounts;
- Reports from Local Healthwatch;
- New or existing peer review schemes;
- Themed inspections.

Recommendation 50

The Care Quality Commission should retain an emphasis on inspection as a central method of monitoring non-compliance.

Recommendation 51

The Care Quality Commission should develop a specialist cadre of inspectors by thorough training in the principles of hospital care. Inspections of NHS hospital care providers should be led by such inspectors who should have the support of a team, including service user representatives, clinicians and any other specialism necessary because of particular concerns. Consideration should be given to applying the same principle to the independent sector, as well as to the NHS.

Recommendation 52

The Care Quality Commission should consider whether inspections could be conducted in collaboration with other agencies, or whether they can take advantage of any peer review arrangements available.

Recommendation 53

Any change to the Care Quality Commission's role should be by evolution – any temptation to abolish this organisation and create a new one must be avoided.

Recommendation 54

Where issues relating to regulatory action are discussed between the Care Quality Commission and other agencies, these should be properly recorded to avoid any suggestion of inappropriate interference in the Care Quality Commission's statutory role.

Recommendation 55

The Care Quality Commission should review its processes as a whole to ensure that it is capable of delivering regulatory oversight and enforcement effectively, in accordance with the principles outlined in this report.

Recommendation 56

The leadership of the Care Quality Commission should communicate clearly and persuasively its strategic direction to the public and to its staff, with a degree of clarity that may have been missing to date.

Recommendation 57

The Care Quality Commission should undertake a formal evaluation of how it would detect and take action on the warning signs and other events giving cause for concern at the Trust described in this report, and in the report of the first inquiry, and open that evaluation for public scrutiny.

Recommendation 58

Patients, through their user group representatives, should be integrated into the structure of the Care Quality Commission. It should consider whether there is a place for a patients' consultative council with which issues could be discussed to obtain a patient perspective directly.

Recommendation 59

Consideration should be given to the introduction of a category of nominated board members from representatives of the professions, for example, the Academy of Medical Royal Colleges, a representative of nursing and allied healthcare professionals, and patient representative groups.

Recommendation 60

The Secretary of State should consider transferring the functions of regulating governance of healthcare providers and the fitness of persons to be directors, governors or equivalent persons from Monitor to the Care Quality Commission.

Recommendation 61

A merger of system regulatory functions between Monitor and the Care Quality Commission should be undertaken incrementally and after thorough planning. Such a move should not be used as a justification for reduction of the resources allocated to this area of regulatory activity. It would be vital to retain the corporate memory of both organisations.

Recommendation 62

For as long as it retains responsibility for the regulation of foundation trusts, Monitor should incorporate greater patient and public involvement into its own structures, to ensure this focus is always at the forefront of its work.

Recommendation 80

A finding that a person is not a fit and proper person on the grounds of serious misconduct or incompetence should be a circumstance added to the list of disqualifications in the standard terms of a foundation trust's constitution.

Recommendation 81

Consideration should be given to including in the criteria for fitness a minimum level of experience and/or training, while giving appropriate latitude for recognition of equivalence.

Chapter 12
Professional regulation

Key themes

- The General Medical Council (GMC) and the Nursing and Midwifery Council (NMC) have been largely reactive to individual complaints against identifiable individuals which may suggest unfitness to practise on the part of unidentified doctors and nurses.
- Stafford demonstrated a lack of referrals by professionals to their regulators when they have concerns.
- The Trust failed to have a proper policy for referring clinicians to professional regulators.
- Regulators should themselves refer or flag cases of concern with professional regulators, either by complying more properly with their current memoranda of understanding or by clarifying the terms of these.
- The NMC and the GMC need to develop a close working relationship with the Care Quality Commission (CQC).
- Patients are often not aware of the existence and procedure for complaining to the NMC and the GMC.
- The NMC has failed properly to define its role or that of its representatives in the NHS.
- Doctors have been reluctant to accept standard processes and to engage with team and management roles.

Introduction

12.1 This chapter considers the involvement of the professional regulators with jurisdiction over the registration of healthcare professionals in the affairs of the Trust. Insofar as the same organisations have training responsibilities, these are addressed in *Chapter 18: Medical training*.

12.2 In truth, little came to the attention of the professional regulators to indicate that there was more fitness to practise issues at Stafford than elsewhere. Given what is now known about the standard of service being delivered there, this may seem surprising, but the regulatory operational model of the regulators depends on complaints – and if there are no complaints no investigation is likely to follow.

General Medical Council

Statutory framework

12.3 The GMC is a statutory body that was established in 1858. Its main statutory objective is "to protect, promote and maintain the health and safety of the public."[1]

12.4 It does this by ensuring proper standards in the practice of medicine. The GMC's role is to protect patients. Whilst it is funded through registration fees paid by registrants, its role is not to represent doctors.

12.5 Under the statutory provisions of the Medical Act 1983[2] the GMC has four main functions:

- Fostering good medical practice which reflects what the general public and the profession expect of doctors;
- Promoting high standards of medical education and training for medical schools and postgraduate training and for doctors' continuing professional development;
- Keeping up-to-date registers of qualified doctors;
- Dealing firmly and fairly with doctors whose fitness to practise is in doubt.

12.6 Doctors are provisionally registered with the GMC upon completion of their undergraduate medical school training and fully registered after successfully completing the first year of the foundation programme.

12.7 The GMC has statutory functions relating to the education and training of doctors, which are considered elsewhere.

Good medical practice

12.8 The GMC exercises its function of maintaining standards through guidance on professional conduct, performance and medical ethics. This is published in the form of *Good Medical Practice*, which is reviewed periodically.[3] The relevant editions for the period under review by the Inquiry are 2001 and 2006.[4] The GMC also publishes ethical guidance on specific topics such as consent, confidentiality, and end of life care.

12.9 The totality of this guidance forms the basis on which the GMC regulates the registration of doctors and it is made clear that a serious or persistent failure to follow it will put the responsible practitioner's registration at risk.[5] As with all guidance, it is recognised that

1 GMC0001000004 Medical Act 1983 (as amended), section 1A
2 Medical Act 1983 www.legislation.gov.uk/ukpga/1983/54/contents
3 Dickson/GMC WS (Provisional) – GMC00000000013, para 45
4 ND/50 WS0000049971–996; ND/50 WS0000049997–50047
5 Dickson/GMC WS (Provisional) – GMC00000000013, para 48

practitioners must exercise their judgement in relation to the circumstances confronting them, but doctors are expected to be able to justify the decisions they make.

12.10 The appalling stories of care uncovered by the Healthcare Commission (HCC) investigation and the first inquiry are highly unlikely to have happened without multiple lapses from the standards set out in the GMC's guidance.

12.11 The principal duties of a doctor as laid down by *Good Medical Practice* are:[6]

- *Make the care of your patient your first concern;*
- *Protect and promote the health of patients and the public;*
- *Provide a good standard of practice and care:*
 - *Keep your professional knowledge and skills up to date;*
 - *Recognise and work within the limits of your competence;*
 - *Work with colleagues in the ways that best serve patients' interests;*
- *Treat patients as individuals and respect their dignity:*
 - *Treat patients politely and considerately;*
 - *Respect patients' right to confidentiality;*
- *Work in partnership with patients:*
 - *Listen to patients and respond to their concerns and preferences;*
 - *Give patients the information they want or need in a way they can understand;*
 - *Respect patients' right to reach decisions with you about their treatment and care;*
 - *Support patients in caring for themselves to improve and maintain their health;*
- *Be honest and open and act with integrity:*
 - *Act without delay if you have good reason to believe that you or a colleague may be putting patients at risk;*
 - *Never discriminate unfairly against patients or colleagues;*
 - *Never abuse your patients' trust in you or the public's trust in the profession.*

Obligation to report concerns about patient safety

12.12 It is made clear that it is the duty of every doctor to be open about mistakes they have made leading to harm to patients and to report concerns about colleagues or otherwise relating to patient safety.

6 www.gmc-uk.org/guidance/good_medical_practice/duties_of_a_doctor.asp

12.13 This duty is not confined to concerns about colleagues but extends to unsafe systems, equipment and so on:

> *If you have good reason to think that patient safety is or may be seriously compromised by inadequate premises, equipment, or other resources, policies or systems, you should put the matter right if that is possible. In all other cases you should draw the matter to the attention of your employing or contracting body. If they do not take adequate action, you should take independent advice on how to take the matter further. You must record your concerns and the steps you have taken to try to resolve them.*[7]

12.14 When something has gone wrong with the treatment of a patient, the doctor's duty of honesty and integrity requires being open with the patient and others:

> *If a patient under your care has suffered harm or distress, you must act immediately to put matters right, if that is possible. You should offer an apology and explain fully and promptly to the patient what has happened, and the likely short-term and long-term effects.*
>
> *Patients who complain about the care or treatment they have received have a right to expect a prompt, open, constructive and honest response including an explanation and, if appropriate, an apology. You must not allow a patient's complaint to affect adversely the care or treatment you provide or arrange.*[8]

12.15 Mr Niall Dickson, Chief Executive and Registrar at the GMC from January 2010, accepted that the GMC should consider whether this guidance should apply equally to near misses:

> *I think that's a very good point. We are currently reviewing* Good Medical Practice. *In my view, doctors should be open and honest with patients, full stop, and that doesn't necessarily require the condition that harm has been done.*[9]

12.16 When there are concerns about colleagues, these must be reported:

> *You must protect patients from risk of harm posed by another colleague's conduct, performance or health. The safety of patients must come first at all times. If you have concerns that a colleague may not be fit to practise, you must take appropriate steps without delay, so that the concerns are investigated and patients protected where necessary. This means you must give an honest explanation of your concerns to an*

7 ND/50 WS0000050007 *Good Medical Practice* (2006), para 6
8 ND/50 WS0000050016 *Good Medical Practice* (2006), paras 30, 31
9 Dickson T105.121; a consultation on the review of *Good Medical Practice* closed in February 2012 – www.gmc-uk.org/guidance/10051.asp

appropriate person from your employing or contracting body, and follow their procedures.[10]

12.17 In the absence of "appropriate local systems", or where local systems appear not to have resolved the problem, the doctor should report the matter to a regulator.[11]

12.18 The doctor is also obliged to cooperate fully with any formal inquiry into the treatment of a patient and any inquest or other formal inquiry into a patient's death.[12]

12.19 Mr Dickson explained why the GMC considers that the duty of doctors is to report concerns to their employer first, rather than to to a regulator:

I think it is our view that if you see something wrong in the first instance, then you should bring it to the attention locally as a first step, rather than immediately contact the GMC. But I don't want to suggest that we're in any way reluctant to accept people coming to us or seeking advice or making contact with us, as many thousands do. But in the first instance, when somebody sees a patient safety concern, apart from the fact the speed with which it would be dealt with, the best place to raise it is locally.[13]

12.20 Dr Peter Daggett, a General Physician at the Trust during the relevant period, suggested to the Inquiry that reporting concerns about an individual was an exceptional event, not just at Stafford but throughout the country.[14] Mr Dickson accepted this was the case to some extent, but commented that it is less exceptional than it used to be.[15]

12.21 Mr Dickson accepted that it was necessary for the GMC, among other organisations, to change the professional culture to promote such reporting:

The events at the Trust suggest that the culture of the organisation was severely compromised and, judging by some of the comments made to the Inquiry, this had a negative impact on the way that individuals within that organisation behaved. It is very difficult to measure the impact of cultural change and we are one of a number of organisations who should be helping to drive this change.[16]

It is quite clear, and it is the thing that concerns me, that at Mid Staffs there must have been significant numbers of doctors who metaphorically walked on the other side of the ward. They were not following our advice.

10 ND/50 WS0000050021 *Good Medical Practice* (2006), para 43
11 ND/50 WS0000050021 *Good Medical Practice* (2006), para 44
12 ND/50 WS0000050027 *Good Medical Practice* (2006), para 68, 69
13 Dickson T105.111
14 Daggett T46.146
15 Dickson T105.114–116
16 Dickson WS0000048839, para 132

Now, of course, as somebody remarked since the Ten Commandments, people have not always followed guidance and rules. But I think there is a duty on us, as the regulator, to redouble our efforts to try and embed this in the profession, and I know Ian Kennedy remarked, in his evidence to you, that he thought that Good Medical Practice *had not been the cultural catalyst that was hoped. I would disagree with that.*

I think, and it's impossible to identify its role, but what's happened over the last 15 years in medicine I think has been quite significant. I think doctors are much more open than they were, they're less paternalistic than they were and they're much more likely to report each other and to recognise it, but I entirely accept there's quite a long way to go.[17]

12.22 However, he did not think the GMC was necessarily the correct place to report a concern about a system as opposed to an individual:

Dr Daggett I think elsewhere in that statement, was making the point that the GMC wasn't the right place to go because this was a whole system that was wrong, rather than an individual, and I think that's a fair point he makes, that the difficulty of saying, "How do I go to the GMC? I'm not complaining about Dr X or Dr Y, I'm saying this whole place is not functioning properly", and I can understand the difficulty with that, though I think there are places he can and should be able to go as a result of that.[18]

Maintaining and improving performance

12.23 The guidance requires doctors to work with their colleagues "to maintain and improve the quality of your work and promote patient safety".

12.24 The actions that are required to bring this about include:

- Maintaining a record of information and evidence, drawn from the doctor's medical practice;
- Reflecting regularly on his or her standards of medical practice;
- Participation in regular and systematic audit and systems of quality assurance and quality improvement;
- Constructive response to the outcome of audit, appraisals and performance reviews, and undertaking further training where necessary;
- Cooperation with confidential inquiries, and adverse event recognition and reporting, to help reduce risk to patients.[19]

17 Dickson T105.116–117
18 Dickson T105.114
19 ND/50 WS0000050011 *Good Medical Practice* (2006), para 14

Doctors as managers

12.25 The GMC has separate guidance for doctors who are managers. This makes it clear that the principles of *Good Medical Practice* continue to apply to medically qualified managers, even where their post could be taken by a person who is not medically qualified or registered.[20] It is recognised that the circumstances of medically qualified managers vary widely but the overall requirements are:

> *You should do your best to make sure that:*
>
> - *Systems are in place to enable high quality medical services to be provided;*
> - *Care is provided and supervised only by staff who have the appropriate skills (including communication skills), experience, training and qualifications;*
> - *Significant risks to patients, staff and the health of the wider community are identified, assessed and addressed to minimise risk, and that they are reported in line with local and national procedures;*
> - *The people you manage (both doctors and other professionals) are aware of and follow the guidance issued by relevant professional and regulatory bodies, and that they are able to fulfil their professional duties so that standards of practice and care are maintained and improved;*
> - *Systems are in place to identify the educational and training needs of students and staff, including locums, so that the best use is made of the time and resources available for keeping knowledge and skills up to date;*
> - *All decisions, working practices and the working environment are lawful, with particular regard to the law on employment, equal opportunities and health and safety;*
> - *Information and policies on clinical effectiveness and clinical governance are publicised and implemented effectively.*[21]

Fitness to practise procedure

Statutory framework

12.26 The GMC has a statutory duty to investigate information calling into question the fitness to practise of a registered medical practitioner. Fitness to practise may be found lacking due to concerns over the health, competence, capability or conduct of a practitioner. The exercise is forward looking: it must be determined whether, having regard to the facts proved, the practitioner is now fit to practise.

20 GMC0003000084–85 *Management for Doctors* (2006) (replaced March 2012), General Medical Council, paras 4–5
21 GMC0003000087 *Management for Doctors* (2006) (replaced March 2012), General Medical Council, para 12

12.27 Where it is found that a practitioner lacks fitness to practise, a range of sanctions is available:

- Warning;
- Undertakings;
- Conditions imposed on registration;
- Suspension;
- Removal from the register.[22]

Procedure

12.28 On receipt of such information there is a "triage" process to determine whether it raises a question about a doctor's fitness to practise. If it could never do so, the case is closed. If the information calls into question the doctor's fitness, it is referred for a full investigation, called "stream 1". If it does not in itself raise such a question but would do so as part of a wider pattern of behaviour, the GMC will make inquiries of the doctor's employers to establish if they have wider concerns (a "stream 2" investigation).[23]

12.29 On completion of this stage of the investigation, the case is referred to two case examiners, one medical and one non-medical, who decide by reference to the regulations whether the allegation should be referred for adjudication. They so refer where it is decided that there is a reasonable prospect of establishing that the doctor's fitness to practise is impaired to a degree justifying action on his or her registration. The options open to the case examiners are to conclude the case with no further action, issue a warning, agree undertakings with doctors to restrict their practise, or refer the case for adjudication to a Fitness to Practise Panel (now the Medical Services Tribunal).[24]

12.30 Interim powers are available to make an order suspending or imposing conditions on the doctor's registration pending the outcome of the process.[25] There can be a number of reasons why proceedings take a long time to come to a conclusion, but Mr Dickson told the Inquiry that the GMC will not hesitate to use these powers, where deemed necessary, to protect patient safety.[26]

12.31 The Medical Services Tribunal conducts a full and formal hearing akin to a trial, usually in public and conducted on an adversarial basis.[27] It is unnecessary to consider here the full detail of the procedure, but if it is determined that the practitioner's fitness to practise is impaired the range of sanctions mentioned above is available. The tribunal has to have regard to the sanctions guidance issued by the GMC.

22 Dickson WS0000048844, para 146
23 Dickson WS0000048842–43, para 143
24 Dickson WS0000048844, para 146
25 Dickson WS0000048845, para 151
26 Dickson WS0000048848, para 160
27 Dickson WS0000048845–47, paras 152–157

Identification of registered practitioners against whom to proceed

12.32 As indicated earlier, the GMC approach to regulating doctors is to act on a complaint or information received. Generally, it does not proactively seek out material that might lead to an investigation unless and until it receives information identifying a registered practitioner whose fitness to practise may be called into question.

12.33 Mr Dickson told the Inquiry that if information was received that did not identify one or more individuals, but revealed circumstances where a fitness to practise issue might have arisen, a formal investigation would not – indeed could not – be commenced.[28] However, the GMC would approach the relevant medical director, postgraduate dean or the CQC to find out more:

> *So I think we're not saying, "Oh, that's nothing to do with us". I think we have that wider responsibility in our work, but obviously the machine that is fitness to practise is dealing with an individual practitioner.*[29]

12.34 Challenged on whether that meant that people potentially responsible for systemic failings might avoid fitness to practise proceedings unless someone else has identified them, Mr Dickson demurred:

> *There certainly could be circumstances where there was systemic failure within an organisation, and without a complainant coming forward, we were able to identify that a doctor was responsible for that system and had caused or was suspected of causing patient safety issues. We could indeed pursue that. So, yes, we could in that sense. But we would be pursuing an individual, it could be the result not of direct patient care that they were giving, but oversight that they had failed to provide, which allowed systemic failure to take place.*[30]

12.35 However the GMC approach to this issue is clearly in a state of evolution as illustrated by another of Mr Dickson's answers:

> *THE CHAIRMAN: Well, if I can put it in a sort of criminal analogy, if you're told about a murder, do you go out and try to find out who committed the murder or do you wait for someone else to do that part of the inquiry and present you with the name of the individual who is alleged to have committed it?*

28 Medical Act 1983, section 35C, www.legislation.gov.uk/ukpga/1983/54/contents. NB The Council can refer identified practitioners to itself under s35CC(3) of the 1983 Act
29 Dickson T105.82–84
30 Dickson T105.84–85

A. I think we're moving towards the latter, and I think – and, again, I don't want to try and imply that employment liaison advisers or the GMC is out to go and hound responsible officers and all the rest of it. But absolutely, if there is systemic failure within an organisation, and we identify – or somebody else identifies to us – individuals who have had responsibility for that, which calls into question their fitness to practise, then we will pursue that.[31]

12.36 Following the first inquiry, the GMC asked for consideration to be given to the Inquiry identifying to it the names of practitioners referred to in the report. This facility was declined due to the fact that the witnesses had given evidence on the basis of an undertaking of confidentiality. Mr Dickson was asked whether that was the limit of inquiry made into that sort of case. He explained that the GMC might take a number of steps, subject to resources. For example, they might follow up a media report by making inquiries into the names of doctors who might have been involved and their responsibilities.[32] He accepted this might be done more now than in the past:

I hope it is. I mean, certainly it's something that I would encourage in my current role. I don't have enough experience to know whether the GMC – how often the GMC has done it. In the recent past I would think it's become more common. If you went back longer, it definitely is different because the GMC was really not concerned about performance issues, even clinical performance issues, in the way that it is now. It used to be concerned mainly with conduct issues.[33]

12.37 There is no internal system for triggering a proactive investigation, but there was, Mr Dickson said, an increasing resource enabling information that might trigger an investigation. He cited the employment liaison advisers and regional advisers being put in place to engage with all employers, allowing the GMC the opportunity of "getting up close and personal". He thought that would enable the GMC to do more proactive investigation.[34]

12.38 The GMC has also invested in its information systems and collects more information from individual doctors. It is therefore in a better position to identify trends that may cause concern.[35]

Fitness to practise cases from the Trust

12.39 The GMC has received information or complaints about 32 doctors working at the Trust during the period under review by the Inquiry. These were received from a wide variety of sources,

31 Dickson T105.85
32 Dickson T105.86
33 Dickson T105.87
34 Dickson T105.87–88
35 Dickson WS0000048850–51, para 166

including patients, relatives, scrutiny of media coverage, the 2009 Royal College of Surgeons (RCS) review[36] and the report of the first inquiry.[37]

12.40 Of this total, 14 doctors had come to the attention of the GMC before the HCC report as a result of 17 complaints. Ten complaints were from patients, three from the Trust, three from colleagues and one from the Strategic Health Authority (SHA).

12.41 Of the 17 complaints, three were closed at the initial assessment stage, five were followed up with the Trust, who confirmed there were no further concerns, eight were investigated and one was the subject of continuing investigation.

12.42 Of the eight complaints investigated, in three cases the outcome was the issuing of advice, in two cases warnings were given, in one case conditions were imposed on the doctor's registration and in two complaints, both in respect of the same doctor, an offer of voluntary erasure from the medical register was accepted.

12.43 Cases against 19 of the 32 doctors were continuing at the time of the GMC evidence, and four of these doctors were subject to interim restrictions on their registration.[38]

12.44 Mr Dickson did not consider that a pattern of concern about the Trust could have been discerned from the cases that arose before the HCC report for a number of reasons:

- At the time the GMC did not look at its cases in a systematic way to try to identify trends;
- Its systems were not capable of conducting that sort of analysis, although this is something now being developed;
- More recently, the GMC has carried out a systematic analysis, but the Trust was not shown to be an outlier. One reason for this may be that the complaints involved a range of specialties, and the number of complaints at Trust level was always likely to be too small for conclusions to be drawn readily.[39]

12.45 Following publication of the HCC report in March 2009, Ms Jackie Smith, the GMC's Head of Investigation at the time, met Dr Heather Wood, the HCC investigator, because the report led the GMC to question whether there were underlying fitness to practise issues. Ms Smith also met Dr Manjit Obhrai, the Trust's then Medical Director. On both occasions she was told that problems with the fitness to practise of individual doctors had not been identified.[40] Looking at the range of concerns raised in that report, that has to be considered a surprising response.

36 JB/14 WS0000043966
37 Dickson WS0000048851–52, paras 169–171
38 Dickson WS0000048852–55, paras 173–182
39 Dickson WS0000048854, para 181; Dickson T105.145
40 Dickson WS0000048856, para 188

12.46 Mr Dickson was concerned to hear that, according to Julie Hendry, Director of Quality and Patient Experience at the Trust, the Trust did not have a policy for referral of individuals to the GMC.[41] He said such a policy was important to enable staff to raise and escalate concerns about colleagues, and for them to know that they were free to contact the GMC or the CQC if they felt their concerns were not being addressed adequately.

Interrelationship between the General Medical Council and employers' disciplinary procedures

12.47 Mr Antony Sumara, the Trust's Chief Executive from July 2009 to August 2012, expressed concern at the effect of GMC proceedings on the Trust's ability to dismiss an unsatisfactory employee:

> *In my experience the regulatory framework for doctors and nurses is extremely protectionist ...* [If] *a doctor is causing harm to patients I would be unable to dismiss him without referring him to the GMC which again is a lengthy process.*[42]

12.48 Mr Dickson rejected this:

> *As far as we are aware, there is no reason why an employer cannot take disciplinary action against a doctor because that doctor is subject to a GMC investigation. The important point is that the employer observes employment law and the relevant NHS guidance and procedures. If there were a risk to patient safety caused by a doctor, we would expect that employer to take action immediately.*
>
> *An employer's disciplinary proceedings and our own fitness to practise investigations can be run in parallel. Although a doctor's employment cannot be terminated solely because of an interim suspension, this does not prevent the Trust from taking disciplinary action based on its own investigation.*
>
> *As a general observation, where performance management systems are not strong, organisations may not be able to take action against an employee because they have not made or kept adequate records and thus do not have enough evidence to act.*[43]
>
> *I think my message, I guess, to employers is, I am trying to speed up, we are trying to speed up our systems, but you should really take whatever action you believe is necessary under employment law to deal with the case as you see it and try and avoid the use of the GMC as being an excuse why it can't be done.*[44]

41 Hendry T52.191; Dickson WS0000048859, para 198
42 Sumara WS(1) WS0000005929, para 78
43 Dickson WS0000048859–60, paras 199–201
44 Dickson T105.128–129

12.49 He did not accept that the prospect of a doctor being suspended for a long time acted as a disincentive to employers from reporting doctors to the GMC:

> *If I were running a trust, I am responsible for an organisation of 3 or GBP 400 million, but my prime objective is to provide safe patient care, then I don't think that should be a consideration. But I accept that that makes it more important than ever that we as an organisation deal with these matters as quickly as we can, but in a way that is consistent with being fair. And undergoing things like performance assessments, as you probably know, can be time-consuming and difficult.*[45]

Revalidation

12.50 On 19 October 2012 the GMC announced that it would be introducing a system of revalidation, which would provide for a five-yearly periodic review by the GMC, based on the process of an annual appraisal of each doctor's fitness to practise, compliance with professional standards and current knowledge.[46] Doctors will need to collect information about their practice, including feedback from patients, other doctors, nurses and other colleagues. The objective of the scheme is to drive up the standard of individual practice, quality of care and to provide assurance to service users and employers.[47] The GMC expects most doctors to have received revalidation by March 2016.

12.51 The key components of the scheme will be:

- A network of Responsible Officers (ROs), usually a senior medical manager of the doctor's employer, with whom each doctor will be connected. ROs will be licensed medical practitioners with statutory duties and subject to a quality assurance programme. The ROs will be responsible for ensuring that doctors are properly managed and supported in maintaining and raising their standards, and for ensuring the existence of fair and effective local systems to identify doctors who fall short of the expected standards. They will be required to report to the GMC on the fitness to practise of doctors causing concern, and to make recommendations for action. They themselves will be accountable to the GMC for their performance in this role;[48]
- A portfolio of evidence of compliance with standards, personal and professional development and so on, which each registered practitioner will be required to maintain.[49]

45 Dickson T105.149
46 www.gmc-uk.org/news/14004.asp
47 Dickson WS0000048860, para 204
48 Dickson WS0000048861–65, paras 207–223
49 *Ready for Revalidation: The Good Medical Practice Framework for appraisal and revalidation*, (March 2011) GMC, p 1

12.52 Mr Dickson was optimistic that the revalidation system would make another Stafford experience less likely to happen:

> *The GMC sets out the values and principles which doctors must follow in their everyday practice. But the GMC is not an employer of doctors and is not in a position to monitor adherence to those principles on a day to day basis in practice across the UK. This requires a more effective local system of clinical governance within healthcare institutions. However, the GMC does have an important contribution to make. A more proactive GMC focused on encouraging good practice, coupled with robust local systems for identifying and acting upon poor practice, should contribute to improving the overall quality of patient care. At the same time it should help to ensure that poor practice can be identified and acted upon more swiftly and before problems become serious ...*
>
> *I would also add that revalidation is based on local systems of appraisal and clinical governance and can act as a driver for developing and strengthening those systems. It will be based on a continuing evaluation of a doctor's fitness to practise rather than a point in time assessment. All appraisals will be based on the principles of* Good Medical Practice *and we believe embedding our standards into the appraisal will remind doctors of the core values and principles that underpin the practice of medicine in the UK. The appraisal should also provide an opportunity for them to reflect on what that might mean for them in their day to day practice.*[50]

12.53 ROs are already in place and, according to Mr Dickson, are in a much stronger position to drive positive change in employers' systems of clinical governance because of their newly acquired responsibility:

> *My impression, and it is only an impression, since the responsible officers arrived in January this year, that already people are starting to, the clue is in the title of the name, that people are starting to take this seriously and they take their relationship as doctors with the GMC pretty seriously.*
>
> *So I'm not suggesting this is a perfect system which can stop this happening. I think it will be a more focused system, because it is about the management of doctors, that we're concerned about, and I think the requirements under revalidation, doctors themselves because they will be saying, "We're not getting the support we need. I haven't got clinical audit and if I don't have the clinical audit, I won't be able to get through my appraisal. So please supply this information, hospital, otherwise we're going to be in trouble."*

50 Dickson WS0000048870–71, paras 246–247

So I think there are a number of pressures within the system which should make it more effective. My hope is that we can make it more effective over time. In other words, it's an instrument which we will all get better at using over time, but it is something we will be actively using in a way that APS [Approved Practice Settings]*, frankly, is not a system that we're actively using in that way.*[51]

General Medical Council relationships with other organisations

Healthcare Commission and Care Quality Commission

12.54 There is a Memorandum of Understanding between the GMC and a number of other organisations, including the HCC, now the CQC. At the relevant time, it provided that:

The Healthcare Commission and the GMC will share information about trends, concerns, data, approaches and initiatives, which are relevant to the shared aim of helping healthcare providers and registered medical practitioners to provide high quality patient care.[52]

12.55 Mr Dickson, who had not been in office at the GMC at the relevant time, had initially been under the impression that the GMC had not been aware of the investigation until very shortly before the publication of the report.[53] It was later accepted that this was not strictly accurate. The GMC was made aware of the terms of reference on 9 July 2008.[54] There were also conversation about two specific doctors in July and August.

12.56 The GMC received no information about the investigation from the Trust or the Postgraduate Dean (whose involvement is considered in *Chapter 18: Medical training*).[55]

12.57 Asked why he thought this information had not been shared, Mr Dickson suggested:

This is not to excuse either party in this, I do think that systems regulators have tended to see professional regulators only ... at the edge of what ... their main focus is. And I don't think that's just the GMC. And what ... I'm attempting to do, certainly in our relationship with the CQC, is say I don't expect the CQC to be thinking about the GMC morning, noon and night, but I do think they've got to see us as a more integral part of the whole quality matrix. That we're not something that's strange and is done with doctors, we're a patient safety organisation ... and our concerns are about patient safety, and that means we have to work together, and that means that if you're the system regulator – I'm sure there are other things we could do better as well, [as the] *systems regulator you have to*

51 Dickson T105.31–32
52 ND/64 WS0000050300, para 19
53 Dickson T105.76
54 Wood WS(4) WS0000074566, para 18
55 Dickson T105.76

think GMC. You have to think patient safety in relation to all our functions, both our educational ones and our fitness to practise ones as well.[56]

12.58 It is now clear that there was a level at which information was being shared by the HCC about its investigation, but there was a degree of confusion between, and within, the various organisations concerned about its significance and what required to be escalated to higher levels.

12.59 What this answer demonstrates is the apparent difficulty experienced by organisations, who, in principle, are willing to cooperate with each other in determining what is of relevance to one another. In the particular case of the GMC and the CQC, matters may have been improved by the more specific terms of the Memorandum of Understanding signed between them on 11 May 2010.[57] This provides for referral to the GMC of:

- Any concerns and relevant information about a doctor which may call into question his or her fitness to practise;
- Any concerns and relevant information about a healthcare organisation which may call into question its suitability as a GMC Approved Practice Setting (APS);
- Any concerns and relevant information about a healthcare organisation which may call into question its suitability as a learning environment for medical students or doctors in training;
- Any concerns and relevant information about a healthcare organisation which may call into question the robustness of its systems of appraisal and clinical governance.[58]

12.60 In return, the GMC will refer to the CQC any concerns and relevant information about a health or adult social care organisation in which doctors practise or are trained, which may call into question its registration with the CQC.[59]

12.61 Asked why it had taken so long to establish this working relationship with the CQC, Mr Dickson pointed to the negative effects of constant reorganisation:

I do not believe the relationship between system and professional regulators has been helped by the constant reorganisations to which the former have been subjected.[60]

56 Dickson T105.80–81
57 CQC00050000041 Memorandum of Understanding between the Care Quality Commission and the General Medical Council (11 May 2010)
58 CQC00050000043 Memorandum of Understanding between the Care Quality Commission and the General Medical Council (11 May 2010), para 12
59 CQC00050000043 Memorandum of Understanding between the Care Quality Commission and the General Medical Council (11 May 2010), para 13
60 Dickson WS0000048875, para 265

I think the problem in this area has been that system regulators have come and gone. I think we have had three or, you could argue, four in the last ten years. I do think that these relationships depend on having, first of all, good relationships at the top of the organisation and clear goals about how you share information and rather than just rather waffly memorandums of understanding, and that's what we're seeking to get with CQC.

The short answer to the question is I don't know whether it's better or worse than under the Healthcare Commission. I think we now have in place a good contact system. I think we will get significantly better when we get regional people on the ground, and we're going to have not only these employment liaison advisers who would certainly be contacting about fitness to practise issues, but we're also having regional people ourselves who will link in with the CQC regional people, and I would expect transfers of information to be better than they have been in the past because of that.[61]

Nursing and Midwifery Council

12.62 The GMC has a Memorandum of Understanding with the NMC that also provides for a sharing of information. Pursuant to this, the GMC did refer a number of nurses to the NMC following a hearing in 2010. In the case of the Trust, the GMC met with the NMC and this led to a series of meetings with patient groups, and cases being opened against four doctors.[62]

Royal Colleges

12.63 The GMC has a necessary relationship with the medical Royal Colleges in relation to its education training responsibilities, which is considered in *Chapter 18: Medical training*.

12.64 The 2007 the Royal College of Surgeons (RCS) peer review team report[63] has been described in *Chapter 2: The Trust*.[64] The report found cause for concern at the lack of cooperation between certain surgeons, lack of leadership and a generally dysfunctional department. This was not shared with the GMC.[65]

12.65 A further review was conducted in 2009[66] and raised significant concerns with the cases of four of the surgeons. These included:

- Poor judgement and decision-making;
- Lack of current knowledge and suboptimal post-operative care;

61 Dickson T105.68
62 Dickson WS0000048876, para 269
63 JB/9 WS0000043904
64 JB/6 WS0000043864
65 Dickson T105.141
66 JB/15 WS0000043990

- Decisions taken by the colorectal multidisciplinary team had been overturned by individual surgeons and non-specialist surgeons operating on colorectal patients in an emergency situation, who had then failed to liaise with or hand the patients back to the colorectal team, as would be the accepted best practice;
- There was reference within the report to the Trust providing care that was "grossly negligent".

12.66 The surgical division was described as "dangerous" and 43 recommendations were made to the Trust. The review stated that the alternative to immediate urgent action was the closure of the department. Some of the issues identified had persisted since the earlier review. Mr Black, then President of the RCS, accepted that evidence of dysfunction in a department represented a significant risk to patients.[67] He described the 2009 report as being one of the most outspoken reports ever produced by the College.[68]

12.67 In spite of these findings, Mr Black gave evidence that, in line with usual practice, the College did not report it to the GMC.[69] His explanation was as follows:

> *The Case Review Report refers to so many badly managed cases that it would be difficult to single out any particular surgeon. It was for the Trust to take a view based on the findings of the review and refer individuals to the GMC if it so wished.*[70]

12.68 With the benefit of hindsight Mr Black accepted that a referral to the GMC ought to have been recommended.[71]

12.69 In each case the report findings could have been read as raising concerns about the fitness to practise of identifiable individuals. However, Mr Dickson pointed to the Trust as having had the responsibility to disclose these reports, rather than the RCS. He was in no doubt as to what effect such disclosure would have had:

> *Q. Can we take it that you accept on behalf of the GMC that you did not spot this as a failing organisation?*
>
> *A. No, we did not.*
>
> *Q. You've now read, I suspect, the Royal College of Surgeons' reports ...*
>
> *A. I have.*

67 Black T106.175
68 Black T106.193
69 Black WS0000043785, para 67
70 Black WS0000043785, para 67
71 Black WS0000043786, para 68

Q ... both for 2007 and then the rather more powerful report in 2009. Having read those, do you think that the GMC processes were in fact engaged when they should have been?

A. No, I think they should have been engaged earlier and I think we should have been told about the Royal College of Surgeons' report before we were.

Q. By whom?

A. I think the prime responsibility is the Trust, as the client who is receiving the report ... I would have hoped that within the report itself, and maybe this is a criticism of us as much of the College, but I would have hoped that they would have reflected on the regulatory implications of the words which they were putting down, such as "dangerous" and "the most dysfunctional team". I think, from memory, those were expressions that were used. Those should have rung alarm bells at the Trust and at the College, or those who were compiling the report about the need to alert the GMC to what was happening here.

And I would hope, again, thinking [about] *this in the positive way, I think we now have a closer relationship with the Trust and I think that we will have closer relationships with trusts as a whole. So I would expect if similar reports emerged in future, that they would alert us immediately.*[72]

12.70 These reports contained information unequivocally suggesting that doctors were in breach of the requirements of *Good Medical Practice* and that patient safety was at risk. They also exposed issues of clinical governance suggestive that the guidance of the GMC to managers was not being observed. In these circumstances, any doctor coming into possession of this report was likely to be under a duty to report the matter if the concerns raised were not being resolved. By 2009 it was clear that that the concerns identified in 2007 had persisted. Indeed, the situation had deteriorated. While there was much else for the Trust to do in response to these reports, disclosure to the GMC was certainly one step that should have been taken.

12.71 Mr Black was clearly right to concede that the report should have recommended referral to the GMC. Given the obligations of *Good Medical Practice*, it might be thought that the College should itself have shared the report with the GMC.

12.72 Mr Black welcomed the impending "duty of cooperation" regulations, which would foster more openness and, in his opinion, strengthen the College's influence on the standards of practice. He considered that an imposition of a duty to share reports was desirable.[73]

72 Dickson T105.141
73 Black T106.207–208

Conclusions with regard to the General Medical Council

12.73 *Good Medical Practice* is a sound basis from which to judge the fitness to practise of doctors. It gives highest priority to the safety of patients and the maintenance of public confidence in the profession, and sets out clearly, albeit at a relatively high level, the standards to be observed. It contains sufficient flexibility to cater for individual circumstances, and preserves the independence of clinical judgement.

12.74 This is not the place to reflect generally on the procedures of the GMC in fitness to practise cases, but one particular concern that has arisen from the Stafford experience has been the absence of any systematic, proactive investigation triggered by information not identifying individual doctors. While Mr Dickson did his best to persuade the Inquiry that such concerns were looked at, there is clearly an element of chance about this in the absence of a clear policy. Historically, the GMC has only investigated specific complaints about identified individuals, and its statutory framework is drafted from that premise, although it does not prevent a more proactive approach to monitoring fitness to practise or to investigating concerns even where individual doctors have not as yet been identified. It is, however, important to remember that the GMC is the regulator of individual registered practitioners and not the system as a whole. Therefore, it is able, if it sees fit to do so, to investigate systemic failures and then take proceedings against individuals it identifies as being professionally responsible.

12.75 Without a clear policy, neither the public nor trusts will be aware of the circumstances in which a generic complaint or report, not in itself identifying individual registered practitioners, can be made to the GMC.

12.76 If the GMC is to be effective in looking into generic complaints and information, it will probably need either greater resources or better cooperation with the CQC and other organisations such as the Royal Colleges to ensure that it is provided with the appropriate information. Even if that is achieved, the GMC needs to be alert to information about system failures of the sort that may indicate fitness to practise concerns, relating not only to front-line clinicians but also clinically qualified managers and leaders. For that purpose the GMC must ensure that the information it does receive or obtain is analysed by persons qualified to discern these possibilities. The GMC is emphatically not a systems regulator, but it cannot ignore the implications for individual registered practitioners. The GMC has told the Inquiry that it is developing a more proactive role through measures such as monitoring news media and other sources of information, and then taking action without waiting for a complaint. This development is to be welcomed, and, as it recognises, pursued and strengthened in conjunction with its regulatory partners.

12.77 The GMC has suffered in the past from poor cooperation from other organisations. The Inquiry has seen evidence of a failure to disclose information raising serious concerns in the form of

the two RCS reports. It should have occurred to both the Trust leadership and the Royal College that the GMC should have sight of them. Steps must be taken to systematise the exchange of information between the royal colleges and the GMC, and guidance issued for use by employers of doctors to the same effect.

12.78 The advantages of peer review is considered in *Chapter 21: Values and standards*, but the GMC should have regard to the possibility of commissioning reviews where concerns are raised in a generic way, in order to be advised whether there are individual concerns. Such reviews could be jointly commissioned with the CQC in appropriate cases.

Nursing and Midwifery Council

Statutory framework

12.79 The NMC regulates nurses and midwives in England, Wales, Scotland, Northern Ireland, the Channel Islands and the Isle of Man. It was established in 2001 to replace the United Kingdom Central Council for Nursing, Midwifery and Health Visitors (UKCC). Its aim is to safeguard the health and well-being of persons using or needing the services of its registrants. It does this by:

- Registering all nurses and midwives and ensuring that they are properly qualified and competent to work in the UK;
- Setting standards of education, training, conduct and performance for nurses and midwives;
- Ensuring that nurses and midwives maintain those standards;
- Ensuring that midwives are safe to practise by setting rules for their practice and supervision;
- Maintaining fair processes for investigation of allegations made against registered nurses and midwives.[74]

12.80 The training functions of the NMC are considered in *Chapter 23: Nursing*.

12.81 The NMC's jurisdiction extends only to individual registered nurses and midwives and not to healthcare support workers. The lack of regulation of such workers is also considered in *Chapter 23: Nursing*.

12.82 The NMC must act on allegations that a nurse or midwife's fitness to practise is impaired by misconduct, lack of competence, a conviction or caution for a criminal offence, health, or the finding of another health or social care regulator.[75]

74 Weir-Hughes WS0000047480, para 6
75 Weir-Hughes WS0000047493, para 59

12.83 The assessment of fitness to practise comprises three practice committees, the Investigating Committee, the Conduct and Competence Committee and the Health Committee.

Code of conduct

12.84 Similarly to the GMC, in order to fulfil its function of establishing standards for education, training, conduct and performance for nurses and midwives and its responsibility for enforcing those standards, the NMC publishes *The Code: Standards of conduct, performance and ethics for nurses and midwives*, which sets out standards that are enforced through its fitness to practise function.[76] Compliance with *The Code* is mandatory, and it is enforced against individuals. It is reviewed and revised on a three-yearly basis. In his statement Professor Dickon Weir-Hughes, then Chief Executive of the NMC, described *The Code* as the key tool in safeguarding the health and well-being of the public. It forms the benchmark against which to measure a registrant's conduct or competence.[77]

12.85 *The Code* is shorter than *Good Medical Practice* but contains many of the same features, adapted for the nursing profession. Amongst the provisions of the version published in 2008 are the following:

> *The people in your care must be able to trust you with their health and well-being.*
>
> *To justify that trust, you must:*
>
> - *Make the care of people your first concern, treating them as individuals and respecting their dignity;*
> - *Work with others to protect and promote the health and well-being of those in your care, their families and carers, and the wider community;*
> - *Provide a high standard of practice and care at all times;*
> - *Be open and honest, act with integrity and uphold the reputation of your profession.*[78]
>
> *...*
>
> *Treat people as individuals.*
>
> *1 You must treat people as individuals and respect their dignity.*
>
> *2 You must not discriminate in any way against those in your care.*
>
> *3 You must treat people kindly and considerately.*

76 DH/2 WS0000047612
77 Weir-Hughes WS0000047482, para 15
78 DH/2 WS0000047614

4 You must act as an advocate for those in your care, helping them to access relevant health and social care, information and support.[79]

...

22 You must work with colleagues to monitor the quality of your work and maintain the safety of those in your care.

...

32 You must act without delay if you believe that you, a colleague or anyone else may be putting someone at risk.

33 You must inform someone in authority if you experience problems that prevent you working within this code or other nationally agreed standards.

34 You must report your concerns in writing if problems in the environment of care are putting people at risk.

35 You must deliver care based on the best available evidence or best practice.

...

38 You must have the knowledge and skills for safe and effective practice when working without direct supervision.

39 You must recognise and work within the limits of your competence.

40 You must keep your knowledge and skills up to date throughout your working life.

41 You must take part in appropriate learning and practice activities that maintain and develop your competence and performance.

Keep clear and accurate records.

42 You must keep clear and accurate records of the discussions you have, the assessments you make, the treatment and medicines you give, and how effective these have been.

43 You must complete records as soon as possible after an event has occurred.

44 You must not tamper with original records in any way.

...

Deal with problems

52 You must give a constructive and honest response to anyone who complains about the care they have received.

79 DH/2 WS0000047615

53 You must not allow someone's complaint to prejudice the care you provide for them.

54 You must act immediately to put matters right if someone in your care has suffered harm for any reason.

55 You must explain fully and promptly to the person affected what has happened and the likely effects.

56 You must cooperate with internal and external investigations.[80]

12.86 As with the GMC, the NMC produces guidance on a number of topics. Nurses are expected to comply with *The Code* and have regard to the guidance. Failure to do so can be visited with disciplinary sanction.

12.87 A cursory consideration of the findings of the HCC investigation and the first inquiry suggests that there have been multiple failures on the part of nurses to comply with *The Code*.

12.88 It was suggested to Professor Dickon Weir-Hughes that the previous version of *The Code* had not placed such emphasis on the care of the patient being the priority. Professor Weir-Hughes had not been involved with the NMC at that time, but, as a long-standing registered nurse himself, he rejected this:

I probably can best speak about this as a registrant myself and certainly even before the NMC, when we ... were the UKCC and had a code then, I was always perfectly clear about the responsibilities. So I struggled to understand how someone could not understand what it is that they were supposed to be doing and the priority they were supposed to be placing upon patient care, for example, regardless of the ... style or writing or the words in this particular version. Because, actually, all of us ... have lived through a number of different iterations of the code, and because it's something that's widely consulted on, and has to be widely consulted on, we do – they will, because of that, inevitably vary slightly. But actually the central themes have always been the same ... So I understand the point you're making completely, ... but I struggle to understand how somebody could have misunderstood their responsibilities, having even read this previous version.[81]

12.89 Professor Weir-Hughes thought that the current Code was adequate to deal with the work of nurses acting as leaders or managers, although the NMC is working on new guidance on the issue.[82]

80 DH/2 WS0000047618–19
81 Weir-Hughes T106.46–47
82 Weir Hughes T106.60

Fitness to practise process

12.90 The NMC's screening team considers all referrals from someone who is not a registered nurse or midwife to determine whether it refers to a registered person, in fact constitutes a fitness to practise matter, or whether sufficient information is provided. If basic requirements are met, the case is referred to the Investigating Committee. This Committee has to decide if there is a case to answer; if there is, the matter is referred to the Conduct and Competence or Health Committees for determination.

12.91 Cases can be determined at relatively informal meetings where simple and where there is no public interest in a public hearing, but most take place at public hearings in a formal adversarial process. If the case is proved, the sanctions available are a caution, imposition of conditions of practice, suspension, or an order for striking off the register.[83]

12.92 There are interim powers of suspension, which can be imposed at any stage of the process.[84]

Past criticism of the Nursing and Midwifery Council

12.93 On 11 June 2008, the Council for Healthcare Regulatory Excellence (CHRE) submitted a *Special Report to the Minister of State for Health Services on the Nursing and Midwifery Council*, addressing "the central question of whether the NMC is fulfilling its statutory functions".[85] The CHRE concluded that, at the time, the NMC "fail[ed] to fulfil [its statutory functions] to the standard of performance that the public has a right to expect of a regulator", and that:

> *There are serious weaknesses in the NMC's governance and culture, in the conduct of its Council, in its ability to protect the interests of the public through the operation of fitness to practise processes and in its ability to retain the confidence of key stakeholders.*

12.94 Six areas "of significant weakness" in the management of the NMC fitness to practise process were identified, including the absence of an IT-based case management system, the poor quality of correspondence, which was sometimes insensitive, misleading and discouraging of complaints, and delays throughout the process. The NMC made a number of commitments to improving its work.[86]

12.95 The progress of the NMC was reviewed as part of the CHRE annual performance reviews in 2008/09 and 2009/10. These highlighted that serious concerns remained about the NMC's performance, particularly in relation to customer care, timeliness and the recording of decisions.[87] In a specially commissioned *NMC Progress Review*, published in January 2011,

83 The process is outlined at Weir-Hughes WS0000047495–98, paras 71–92
84 Weir-Hughes WS0000047498, paras 93–95
85 JB/1 WS0000050724
86 JB/1 WS0000050727–29
87 JB/2 WS0000050763, para 1.4

the CHRE concluded that the NMC had made a number of significant improvements since the Special Report in 2008 in both its fitness to practise procedures and general governance arrangements. However, there was still concern "about the seriousness of the amount and nature of the improvements that the NMC has to make".[88] In particular, the CHRE concluded that:

> *Third party feedback we have received, feedback from the NMC's own committee members and the external audit the NMC commissioned on the quality of its committees clearly show that the administration of the fitness to practise process is poor.*

12.96 Examples of poor administration identified included the non-availability of guidance documentation, poor committee allocation, breaches of confidentiality, inaccurate notifications to registrants and poor witness liaison.[89]

12.97 The CHRE published a *Strategic Review of the NMC* on 3 July 2012, after the Inquiry hearings had come to an end.[90] The report concluded:

> *The NMC has continued to carry out its public protection duties, although not as well as it should but, as its stakeholders make clear, it is not inspiring confidence in the professions or in professional regulation.*
>
> *As we said in our interim report* [published in April 2012]*, at the heart of the NMC's failure to succeed lies confusion over its regulatory purpose, lack of clear, consistent strategic direction, unbalanced working relationships and inadequate business systems.*
>
> *...*
>
> *The main problem rests with the NMC's performance in fitness to practise. CHRE consistently highlighted problems with its performance of this regulatory function but only recently has the organisation shown any real determination to address its shortfalls. It has underinvested in fitness to practise compared to other regulators, it needs to have a clearer strategy for turnaround, better focus on planning and a more streamlined approach to delivery.*

12.98 The CHRE did identify that by the time the review had concluded, "there were some encouraging signs that foundations for change were beginning to be put in place".[91]

88 JB/2 WS0000050790
89 JB/2 WS0000050788
90 *Strategic Review of the Nursing and Midwifery Council: Final Report* (3 July 2012), Council for Healthcare and Regulatory Excellence, https://www.CHRE.org.uk/satellite/485www.CHRE.org.uk/_img/pics/library/pdf_1333646173.pdf
91 *Strategic Review of the Nursing and Midwifery Council: Final Report* (3 July 2012), Council for Healthcare and Regulatory Excellence, p 4–6

12.99 Professor Dickon Weir-Hughes, then Chief Executive of the NMC, giving evidence before this latest report had been published, was asked why it had taken so long to address the perceived deficiencies in the organisation. He said:

> *... I simply don't know why it wasn't ... I can speak more confidently I think about what I found when I arrived which will have been some of those things which were carry-overs from the time you're referring to. I think a lack of basic management process, a lack of performance management of staff, a lack of training, a lack of proper procedures for dealing with serious incidents or serious cases. I think perhaps a lack of enthusiasm to challenge our cumbersome legislation, which is difficult and makes one rather unpopular but nevertheless it's important to do. So perhaps ... just an acceptance of what was there, rather than any thought of actually challenging it and making it better.*[92]

Generic complaints

12.100 Like the GMC, the NMC has not historically investigated cases unless it has received information about a specific identified or identifiable registrant. It has acted on information received, rather than proactively seeking out causes for concern. No doubt for this reason, it has had an information system that does not permit a great deal of analysis.

12.101 The NMC informed the Inquiry that searches of its records had only identified three cases concerning the quality of care of nursing at the Trust in the period under review. It was not made aware of any systemic failing. It was only possible to discover these three cases by a search referring to the names of the Trust's directors of nursing: the system did not allow a search by reference to place of employment or employing trust.[93] The Trust's own records suggested there had only been one referral between 1 April 2005 and 17 June 2009.[94]

12.102 Professor Weir-Hughes told the Inquiry that the NMC now has a new management structure, new members of staff, a new screening team and an IT case management system, which will allow for the more effective processing of cases. While this may expedite the processing of referred cases, a much-needed facility if the above reports are to be accepted, the NMC is also making improvements to its data management allowing for greater analysis of fitness to practise statistics. It now builds up information from multiple sources enabling it to have a broader picture than before. This should assist it in becoming a more proactive regulator.[95]

92 Weir-Hughes T106.111–112
93 Weir-Hughes WS0000047503, paras 112, 114
94 Weir-Hughes WS0000047505, para 120
95 Weir-Hughes T106.109–111

12.103 Following the Stafford experience Professor Weir-Hughes told the Inquiry that the NMC was becoming increasingly proactive:

> *I think I've been very keen, since I came into post in 2009, to make the NMC into a much more proactive organisation. And that, if I'm honest, has not necessarily been welcomed in every corner, but we're clearly not there to be popular ... I have been very keen that we move in a direction of proactivity, because really, although fitness to practise is a very, very important part of our work, it is really a bit like closing a stable door after the horse has bolted, and our desire, of course, would be to see far fewer fitness to practise cases, because they're – you know, not – because people aren't doing things that require them to be referred, not because they're not being referred.*
>
> *So I think the whole team that we have now is very enthusiastic about being proactive, which is good.*[96]

12.104 This answer was given in the context of the issuing of guidance for nurse managers, obviously a positive and proactive step in itself, but not in relation to the investigation of concerns. However, the NMC has taken a number of steps designed to allow it to be more interventionist:

- The approach to fitness to practise cases has changed. More use is made of the power possessed by the Registrar to refer cases to fitness to practise procedures without a referral from a third party;[97]
- A report by Dame Elizabeth Fradd was commissioned and delivered in September 2010 to address the regulatory gap between NMC activity and the systems regulators' activity. This recommended that the NMC develop a critical standards intervention system to assist in identifying possible systemic failures. This will require the recruitment of experienced staff, a framework of indicators, and a system for collating and analysing information. The NMC is actively working towards implementation. There is, however, a limit to the progress that can be made in this direction, because the statutory powers of the NMC do not permit it to investigate organisations as opposed to individuals. The report also recommended requiring nursing directors to report annually on compliance with NMC standards in their organisations.[98]

Referrals in relation to nurses at the Trust

12.105 As has been seen, very few referrals of nurses at the Trust were made. One example of the apparent reluctance of the then Trust management to grasp the nettle with regard to alleged misconduct reported by a whistleblower, has been considered in *Chapter 2: The Trust*.

96 Weir-Hughes T106.64–65
97 Weir-Hughes WS0000047522, paras 183–184
98 Weir-Hughes WS0000047519–21, paras 174–182

12.106 Asked why he thought there had been so few referrals, Professor Weir-Hughes speculated that there may have been a culture of isolation that overrode the professional responsibility to report concerns.[99] Recognising this issue in 2009, the NMC undertook a project to review guidance and support offered to registrants, involving public meetings and the involvement of organisations such as Public Concern at Work. The guidance, *Raising and Escalating Concerns*, was finalised and published in November 2010 and circulated to all registrants.[100] Professor Weir-Hughes considered that the guidance had been shown to be effective because of the number of whistleblowers who now report concerns to the NMC.[101] With regard to the inevitable fears whistleblowers will have about recrimination, the NMC frequently works with the Royal College of Nursing (RCN) to ensure that informants receive support in addressing any such problems.[102]

Interrelationship between the Nursing and Midwifery Council process and employers' disciplinary process

12.107 Professor Weir-Hughes said it was important for nurse directors to refer cases to the NMC when internal disciplinary procedures were being taken for matters involving a breach of the Code. Otherwise, there would be nothing to stops nurses moving off to another employer and continuing to practise, even if there was a need to protect the public. He understood that it could sometimes be difficult for nurse managers to know when the boundary had been crossed between a matter that could be dealt with locally and one that required NMC intervention. He counselled erring on the side of referral.[103]

12.108 Professor Weir-Hughes told the Inquiry that a rolling programme of meetings with nurse directors and others is being held to explain the role of the NMC and how they should be working together.

The profile of the Nursing and Midwifery Council

12.109 Professor Weir-Hughes accepted that public awareness of the NMC was not as good as it might have been, although there had recently been a more prominent NMC media presence and an increase in referrals both from employers and members of the public.[104]

12.110 He thought that an obligation on healthcare providers to provide complainants with information about the NMC would be helpful.[105]

99 Weir-Hughes WS0000047505, para 121
100 Weir-Hughes T106.48; Weir-Hughes WS0000047517–18, paras 164–168; DH/25 WS0000048110
101 Weir-Hughes T106.49
102 Weir-Hughes T106.56
103 Weir Hughes T106.77–78
104 Weir-Hughes T160.79–80; Weir-Hughes WS0000047505, para 121
105 Weir-Hughes T106.80–81

Relationship with the Healthcare Commission and the Care Quality Commission

12.111 The NMC had a Memorandum of Understanding with the HCC providing that significant concerns should be shared mutually, including those arising out of the HCC's investigations and reviews.[106] However, the NMC were not informed formally of the HCC's investigation into the Trust until about two weeks before publication of the report. Professor Weir-Hughes, who was not in post at the time, could not rule out the possibility that knowledge of the investigation existed at some level in the organisation, but stated that it did not feed into any assurance process if the information was there. To him, this illustrated the importance of developing strong professional relationships with the CQC.[107]

12.112 In September 2010 the NMC and the CQC signed a Memorandum of Understanding which defined the circumstances in which the CQC would refer a matter to the NMC and vice versa. Professor Weir-Hughes told the Inquiry that, although the two organisations have a reasonable working relationship, there are still problems over the timely transfer of information. He considered this was contributed to by the CQC not having the benefit of a director of nursing (or other dedicated NMC conduit), as he felt there was something of a lack of understanding about the importance of sharing information with the NMC.[108]

12.113 Once again, this emphasises the importance of all regulatory organisations having, not only high level memoranda of understanding, but a mutual system for allowing each other to know of the actions of the others, and to understand their importance and significance for their own responsibilities.

Conclusions on the Nursing and Midwifery Council

12.114 The NMC's fitness to practise role is based on a Code which, like the GMC's *Good Medical Practice,* has the merit of clarity and simplicity. Criticisms have been suggested of the 2002 version of the NMC's Code for not making clear the priority that has to be given to patients. That criticism is unfounded. Not only is the requirement plain on a reading of the whole of *The Code*, it was also the product of a time when it was probably presumed that no nurse would ever think anything else was the priority. Unhappily, experiences such as that of Mid Staffordshire show that this presumption can no longer be made. The later version of the code remedies this to the extent that is required.

12.115 The NMC's involvement with the Trust and the fitness to practise of its nursing staff was very limited prior to the HCC report. Given what may have been widespread non-compliance with the nursing Code on the part of at least some nurses during the period under review, it is clear that cases which should have been referred to the NMC were not. The systemic failures

106 NMC00020000117 Memorandum of Understanding between the Healthcare Commission and the using and Midwifery Council (January 2008) (historic), paras 13–15
107 Weir-Hughes T106.25–27; Weir-Hughes WS0000047502, para 105
108 Weir-Hughes T106.85–86

in themselves suggest that an investigation into the part played by nurse managers and leaders should have been considered. However, the NMC could not be expected to take such a step unless it received information enabling it to do so. It was not set up as a proactive investigative regulator but one whose principal task was to act on information offered to it, by way of complaint or referral.

12.116 However, if the NMC is to act as an effective regulator of nurse managers and leaders acting in those roles, as well as more front-line nurses, it needs to be equipped to look at systemic concerns as well as individual ones. It does not have to take the place of the systems regulators but it needs to work closely with them and to share their information and analyses on the working of systems in organisations in which nurses are active. It should not have to wait until a disaster has occurred to intervene with its fitness to practise procedures. If concerns are developed, for example at the CQC, either through its Quality Risk Profile system, or the observations of local inspectors communicated to the NMC, it should be able to make a judgement as to whether issues have been raised about nursing fitness to practise and compliance with the nursing Code. Therefore, full access to CQC information in particular is vital. It is not, however, sufficient. The NMC needs to have its own internal capacity to assess systems and launch its own proactive investigations where it becomes aware of concerns which may give rise to nursing fitness to practise issues, even if it is first off unaware of the identity of a registered nurse to whom this applies. It may decide to seek the cooperation of the CQC, but as an independent regulator it must be empowered to act on its own if it considers it necessary and in the public interest. This will require resources, both in terms of appropriately expert staff, data systems and finance. Given the power of the registrar to refer cases without a formal third-party complaint, it would not appear that a change of regulation is necessary. Indeed, as at the time of Professor Dickon Weir-Hughes' evidence, 181 fitness to practise cases had been opened since 2009 without a referral to the NMC by an external agency.[109]

12.117 It is of concern that the administration of the NMC, which has not been examined by this Inquiry, is still found by other reviews to be wanting. It is imperative in the public interest that this is remedied urgently. Without doing so there is a danger that the regulatory gap between the NMC and the CQC will widen rather than narrow.

12.118 The Inquiry was told that the NMC intends to introduce a system of revalidation similar to that being deployed by the GMC. This is highly desirable as a means of reinforcing the status and competence of registered nurses, as well as providing additional protection to the public. However, revalidation is very complex, and it is essential that the NMC has the resources and the administrative and leadership skills to ensure that this does not detract from its existing core function of regulating fitness to practise of registered nurses.

109 Weir-Hughes T106.26–27

12.119 The profile of the NMC needs to be raised with the public, who are the prime and most valuable source of information about the conduct of nurses. All patients should be informed by those providing treatment or care of the existence and role of the NMC together with its contact details. The NMC itself needs to undertake more by way of public promotion of its functions.

12.120 As with the GMC, the length and complexity of NMC procedures may deter nurse employers from referring as many cases as they should. While the NMC does not accept that its regulations require it, there is some evidence of a perception in the wider healthcare world that internal disciplinary action must await the outcome of any NMC proceedings so as not to prejudice them.[110] Given that the prime objective of both types of procedure is to protect patients and the public, it is essential that, so far as practicable, one does not obstruct the progress of the other. In most cases it should be possible, through cooperation, to allow both to proceed in parallel. As Professor Weir-Hughes pointed out, it may be important for the public to be protected by an interim suspension order even if the employer has suspended a registrant under her or his contract of employment, but that otherwise the employer can take its own proceedings before or instead of a referral to the NMC.[111] There is nothing in the NMC's regulations which prevents parallel proceedings, although it appears that it is the NMC's policy generally to await the outcome of the employer's procedures before taking its own action. This may require a review of employment disciplinary procedures to make it clear that the employer is entitled to proceed even if there are pending NMC proceedings.

12.121 It is clear that the role of Director of Nursing is an important and often lonely one in relation to ensuring compliance with the nursing Code, not only in her/his own work, but among the staff of the organisation. The availability of support for those in this role is very important, but it is not clear how the support previously provided by nursing directors at SHAs is to be replaced. The GMC are seeking to rely on the new concept of employment liaison officers to offer some such support. The NMC could consider some similar solution, but if this is impractical, a support network of senior nurse leaders will have to be engaged in filling this gap.

Health and Care Professions Council

Statutory framework

12.122 The Health and Care Professions Council (HCPC) was established (as the Health Professions Council) by the Health and Social Work Professions Order 2001, made under section 60 of the Health Act 1999. The HCPC came into force on 12 February 2002. It is an independent statutory regulator with responsibility for the regulation of the following professions: art therapists, biomedical scientists, chiropodists and podiatrists, clinical scientists, dieticians,

110 Sumara WS(1) WS0000005929, para 78
111 Weir-Hughes T106.74–5

occupational therapists, operating department practitioners, orthoptists, paramedics, physiotherapists, prosthetists and orthotists, radiographers, speech and language therapists, practitioner psychologists and hearing aid dispensers.[112]

12.123 The aims of the HCPC are:

- Maintaining and publishing a public register of properly qualified members of the professions;
- Approving and upholding high standards of education and training, and continuing good practice;
- Investigating complaints and taking appropriate action;
- Working in partnership with the public, and a range of other groups including professional bodies;
- Promoting awareness and understanding of the aims of the council.[113]

12.124 The principal functions of the HCPC are to establish standards of education, training, conduct and performance for members of the relevant professions and to ensure the maintenance of those standards. The main objective in exercising these functions is to safeguard the health and well-being of persons using or needing the services of registrants. The HCPC's statutory powers are complaints-led insofar as it is responsible for regulating individual registrants rather than services. It has no general powers of inspection or oversight. In that regard its functions are similar to those of the GMC and the NMC. The HCPC has a statutory duty to cooperate with the employers of registrants as well as with the regulators of other healthcare professionals.[114]

Code of conduct

12.125 The HCPC has set standards of ethics and performance applicable to all its regulated professions. The standards themselves are expressed very simply:

1 You must act in the best interests of service users.

2 You must respect the confidentiality of service users.

3 You must keep high standards of personal conduct.

4 You must provide (to us and any other relevant regulators) any important information about your conduct and competence.

5 You must keep your professional knowledge and skills up to date.

112 Health and Care Professions Council WS (Provisional) – HPC00000000002
113 *Aims and vision* (as at August 2012), Health and Care Professions Council, www.hpc-uk.org/aboutus/aimsandvision/
114 Health and Care Professions Council WS (Provisional) – HPC00000000003

6 You must act within the limits of your knowledge, skills and experience and, if necessary, refer the matter to another practitioner.

7 You must communicate properly and effectively with service users and other practitioners.

8 You must effectively supervise tasks that you have asked other people to carry out.

9 You must get informed consent to give treatment (except in an emergency).

10 You must keep accurate records.

11 You must deal fairly and safely with the risks of infection.

12 You must limit your work or stop practising if your performance or judgement is affected by your health.

13 You must behave with honesty and integrity and make sure that your behaviour does not damage the public's confidence in you or your profession.

14 You must make sure that any advertising you do is accurate.[115]

12.126 Clearly these standards are somewhat less sophisticated than those produced by the GMC and the NMC but have to be common to a varied collection of professions.

Involvement with the Trust

12.127 The HCPC informed the Inquiry that it had no direct knowledge or information with regard to events at the Trust. It had received no complaints about its registrants there. Therefore, no further evidence was sought.[116]

Overall conclusions

12.128 It has been seen that the GMC and the NMC have both faced similar challenges in regulating the role of healthcare professionals in cases of systems failures. Where there is an effective local system of clinical governance it might be expected that individual cases of suspected impairment of fitness to practise would be referred to the GMC or the NMC without hesitation. So far as the absence of referrals from professionals in the hospital is concerned, this may well have been due to the unhealthy culture described in the first inquiry report. The lack of complaints from the public may well have been due to the lack of profile each organisation has. It is common to see the media mistaking the British Medical Association for the GMC and it is likely that the public suffer from a similar confusion. While both the GMC and the NMC have highly informative internet sites, both need to ensure that patients and other service

115 *Standards of Conduct, Performance and Ethics* (1 July 2008), Health and Care Professions Council, p 3, www.hpc-uk.org/assets/documents/10002367FINALcopyofSCPEJuly2008.pdf
116 Health and Care Professions Council WS (Provisional) – HPC00000000004

users are made aware at the point of service provision of their existence, of their role and their contact details.

12.129 Both the public and professionals may be deterred from referring cases by the apparent complexity of the process and the time taken to resolve cases. Julie Bailey, of Cure the NHS, complained to the Inquiry about her experience pursuing a complaint with the NMC:

> *Well ... as a complainant, it's just a long drawn out process and I've had to constantly ring them to keep me up to date with what's going on. I contacted them last week and they've told me now that – although I haven't received this in writing, that on 22nd December* [2010] *there will be a sort of the first stage of the investigation where they decide if they are going to pursue the complaint. So, here we are now, it must be eight months that I first put in the request, and ... the decision is not going to be taken until 22 December if my complaint is going to be taken further.*
>
> *What I am led to believe for people who have gone through the process, have got experience is the majority of cases aren't pursued because the nurse has now got quite a period without any further blemishes on her record.*[117]

12.130 Without coming to any conclusion on this particular complaint, both organisations need constantly to have in mind the need to explain to complainants what is happening, why it is happening and what is being done about the complaint. While the regulatory process requires the regulator to represent the public interest not the complainant, the latter must be fully supported and, so far as possible, treated as a partner.

12.131 Where referral is absent, as was the case at the Trust, then other means are necessary to ensure that the public is protected. Both organisations need to develop their capacity to examine and investigate concerns even where no named individual has been identified to them. In a case like Stafford there may be many professionals whose role requires examination. At the moment, the impression is that neither the GMC nor the NMC has the capacity or skills to undertake this sort of work. In addition to its own capacity to undertake proactive investigations, and perhaps to minimise the need to do so, both organisations must develop closer working relationships with the CQC – in many cases there should be joint working to minimise the time taken to resolve issues and maximise the protection afforded to the public.

12.132 How this is achieved is an operational matter but one which requires continual public scrutiny. Therefore, the three organisations should be required to produce a joint periodic report on their cooperation and joint achievements.

117 Bailey T10.98–99

12.133 The story of Stafford shows that the conduct of individual doctors and nurses can be relevant to the analysis of the failure of an organisation to perform its duty to its patients. Even in cases involving a single patient there will often, sadly, be lapses in standards by members of both professions. Currently such cases, where they come to light, are dealt with by the relevant professional regulator as if in a silo, applying a differently worded code of conduct, a different approach to sanctions, and by reason of the matters being dealt with in different systems, the possibility of inconsistent outcomes. The previous Government created the Office of the Health Professions Adjudicator, with a view in part towards aligning the procedures, approaches and sanctions of the various healthcare professional regulators. That body has been abolished and its role in this regard transferred to the CHRE, which in December 2012 became the Professional Standards Authority for Health and Social Care (PSA). The PSA, together with the regulators under its supervision, should seek to devise procedures for dealing consistently and in the public interest with cases arising out of the same event or series of events, but involving professionals regulated by more than one body. While it would require new regulations, consideration should be given to the possibility of moving towards a common independent tribunal to determine fitness to practise issues and sanctions across the healthcare professional field. All regulators should exchange details of those members found to be substandard and look at where they are working in order to achieve cross correlation. The abolition of the OHPA, which was to be such a tribunal, need not inhibit the PSA from considering the economic and public interest gains that might be made from such a step.

12.134 Historically, the GMC has only investigated specific complaints about identified individuals, and its statutory framework is drafted from that premise, although it does not prevent a more proactive approach to monitoring fitness to practise.

12.135 Without a clear policy, neither the public nor trusts will be aware of the circumstances in which a generic complaint or report ought to be made to the GMC.

12.136 If the GMC is to be effective in looking into generic complaints and information it will probably need either greater resources, or better cooperation with the CQC and other organisations such as the royal colleges to ensure that it is provided with the appropriate information. Even if that is achieved, the GMC needs to be alert to information about system failures of the sort which may indicate fitness to practise concerns, relating not only to front-line clinicians but also clinically qualified managers and leaders. For that purpose the GMC must ensure that the information it does receive or obtain is analysed by persons qualified to discern these possibilities. The GMC is emphatically not a systems regulator, but it cannot ignore the implications for individual registered practitioners.

12.137 Steps must be taken to systematise the exchange of information between the Royal Colleges and the GMC, and guidance issued for use by employers of doctors to the same effect.

12.138 The advantages of peer review is considered in *Chapter 21: Values and standards*, but the GMC should have regard to the possibility of commissioning reviews where concerns are raised in a generic way, in order to be advised whether there are individual concerns. Such reviews could be jointly commissioned with the CQC in appropriate cases.

12.139 If the NMC is to act as an effective regulator of nurse managers and leaders acting in those roles, as well as more front-line nurses, it needs to be equipped to look at systemic concerns as well as individual ones. It does not have to take the place of the systems regulators but it must be enabled to work closely with them and to share their information and analyses on the working of systems in organisations in which nurses are active. It should not have to wait until a disaster has occurred to intervene with its fitness to practise procedures. If concerns are developed for example at the CQC, either through its Quality Risk Profile system, or the observations of local inspectors, the NMC should be able to make a judgement as to whether issues have been raised about nursing fitness to practise and compliance with the nursing Code. Therefore, full access to CQC information in particular is vital. That is not, however, sufficient. The NMC needs to have its own internal capacity to assess systems and launch its own proactive investigations where it becomes aware of concerns which may give rise to nursing fitness to practise issues. It may decide to seek the cooperation of the CQC, but as an independent regulator it must be empowered to act on its own if it considers it necessary, in the public interest. This will require resources, both in terms of appropriately expert staff, data systems and finance.

12.140 Given the power of the registrar to refer cases without a formal third-party complaint, it would not appear that a change of regulation is necessary, but this should be reviewed.

12.141 It is of concern that the administration of the NMC, which has not been examined by this Inquiry, is still found by other reviews to be wanting. It is imperative in the public interest that this is remedied urgently. Without doing so there is a danger that the regulatory gap between the NMC and the CQC will widen rather than narrow.

12.142 The Inquiry was told that the NMC intends to introduce a system of revalidation similar to that being deployed by the GMC. This is highly desirable as a means of reinforcing the status and competence of registered nurses, as well as providing additional protection to the public. However, revalidation is very complex, and it is essential that the NMC has the resources and the administrative and leadership skills to ensure that this does not detract from its existing core function of regulating fitness to practise of registered nurses.

12.143 The profile of the NMC needs to be raised with the public, who are the prime and most valuable source of information about the conduct of nurses. All patients should be informed by those providing treatment or care of the existence and role of the NMC together with its

contact details. The NMC itself needs to undertake more by way of public promotion of its functions.

12.144 As with the GMC, the length and complexity of NMC procedures may deter nurse employers from referring as many cases as they should. While the NMC may not believe it to be the case, there is a perception in the wider healthcare world that NMC procedures hinder progress with internal disciplinary action, on the basis that such action must await the outcome of any NMC proceedings so as not to prejudice them. Given that the prime objective of both types of procedure is to protect patients and the public, it is essential that, so far as practicable, one does not obstruct the progress of the other. In most cases it should be possible, through cooperation, to allow both to proceed in parallel. This may require a review of employment disciplinary procedures to make it clear that the employer is entitled to proceed even if there are pending NMC proceedings.

12.145 It is clear that the role of Director of Nursing is an important and often lonely one in relation to ensuring compliance with the nursing Code, not only in her/his own work, but among the staff of the organisation. The availability of support for those in this role is very important, but it is not clear how that previously provided by nursing directors of SHAs is to be replaced. The GMC are seeking to rely on the new concept of employment liaison officers to offer some such support. The NMC could consider some similar solution, but if this is impractical a support network of senior nurse leaders will have to be engaged in filling this gap.

Summary of recommendations

Recommendation 222

The General Medical Council should have a clear policy about the circumstances in which a generic complaint or report ought to be made to it, enabling a more proactive approach to monitoring fitness to practise.

Recommendation 223

If the General Medical Council is to be effective in looking into generic complaints and information it will probably need either greater resources, or better cooperation with the Care Quality Commission and other organisations such as the Royal Colleges to ensure that it is provided with the appropriate information.

Recommendation 224

Steps must be taken to systematise the exchange of information between the Royal Colleges and the General Medical Council, and to issue guidance for use by employers of doctors to the same effect.

Recommendation 225

The General Medical Council should have regard to the possibility of commissioning peer reviews pursuant to section 35 of the Medical Act 1983 where concerns are raised in a generic way, in order to be advised whether there are individual concerns. Such reviews could be jointly commissioned with the Care Quality Commission in appropriate cases.

Recommendation 226

To act as an effective regulator of nurse managers and leaders, as well as more front-line nurses, the Nursing and Midwifery Council needs to be equipped to look at systemic concerns as well as individual ones. It must be enabled to work closely with the systems regulators and to share their information and analyses on the working of systems in organisations in which nurses are active. It should not have to wait until a disaster has occurred to intervene with its fitness to practise procedures. Full access to the Care Quality Commission information in particular is vital.

Recommendation 227

The Nursing and Midwifery Council needs to have its own internal capacity to assess systems and launch its own proactive investigations where it becomes aware of concerns which may give rise to nursing fitness to practise issues. It may decide to seek the cooperation of the Care Quality Commission, but as an independent regulator it must be empowered to act on its own if it considers it necessary in the public interest. This will require resources in terms of appropriately expert staff, data systems and finance. Given the power of the registrar to refer cases without a formal third party complaint, it would not appear that a change of regulation is necessary, but this should be reviewed.

Recommendation 228

It is of concern that the administration of the Nursing and Midwifery Council, which has not been examined by this Inquiry, is still found by other reviews to be wanting. It is imperative in the public interest that this is remedied urgently. Without doing so, there is a danger that the regulatory gap between the Nursing and Midwifery Council and the Care Quality Commission will widen rather than narrow.

Recommendation 229

It is highly desirable that the Nursing and Midwifery Council introduces a system of revalidation similar to that of the General Medical Council, as a means of reinforcing the status and competence of registered nurses, as well as providing additional protection to the public. It is essential that the Nursing and Midwifery Council has the resources and the administrative and leadership skills to ensure that this does not detract from its existing core function of regulating fitness to practise of registered nurses.

Recommendation 230

The profile of the Nursing and Midwifery Council needs to be raised with the public, who are the prime and most valuable source of information about the conduct of nurses. All patients should be informed, by those providing treatment or care, of the existence and role of the Nursing and Midwifery Council, together with contact details. The Nursing and Midwifery Council itself needs to undertake more by way of public promotion of its functions.

Recommendation 231

It is essential that, so far as practicable, Nursing and Midwifery Council procedures do not obstruct the progress of internal disciplinary action in providers. In most cases it should be possible, through cooperation, to allow both to proceed in parallel. This may require a review of employment disciplinary procedures, to make it clear that the employer is entitled to proceed even if there are pending Nursing and Midwifery Council proceedings.

Recommendation 232

The Nursing and Midwifery Council could consider a concept of employment liaison officers, similar to that of the General Medical Council, to provide support to directors of nursing. If this is impractical, a support network of senior nurse leaders will have to be engaged in filling this gap.

Recommendation 233

While both the General Medical Council and the Nursing and Midwifery Council have highly informative internet sites, both need to ensure that patients and other service users are made aware at the point of service provision of their existence, their role and their contact details.

Recommendation 234

Both the General Medical Council and Nursing and Midwifery Council must develop closer working relationships with the Care Quality Commission – in many cases there should be joint working to minimise the time taken to resolve issues and maximise the protection afforded to the public.

Recommendation 235

The Professional Standards Authority for Health and Social Care (PSA) (formerly the Council for Healthcare Regulatory Excellence), together with the regulators under its supervision, should seek to devise procedures for dealing consistently and in the public interest with cases arising out of the same event or series of events but involving professionals regulated by more than one body. While it would require new regulations, consideration should be given to the possibility of moving towards a common independent tribunal to determine fitness to practise issues and sanctions across the healthcare professional field.

Chapter 13
Regulation: the Health and Safety Executive

Key themes

- The Health and Safety Executive (HSE) was the only regulator with powers to prosecute during the period with which this Inquiry is concerned, but it was unable or unwilling to do so.
- The HSE oversees exclusively a safety regime of very wide scope and very flexible prosecution powers.
- There is a need to properly define the responsibilities and management of the various healthcare system regulators.
- There should be communication between agencies to avoid duplication of work and to avoid any gaps in the system.
- There is a lack of investigation by the HSE into individual cases raising health and safety issues in clinical contexts.
- There is a lack of systematic audit or analysis of incidents reported to the HSE from the Trust or other institutions.
- The HSE, the Healthcare Commission (HCC), the Care Quality Commission (CQC) and the Department of Health (DH) have, between them, failed to address the regulatory gap between themselves and the HSE.

Introduction

13.1 The Health and Safety Executive (HSE) has had a direct involvement in cases at the Trust. An examination of how it deals with safety issues in hospitals has provided the Inquiry with an opportunity to consider the interface between the HSE's duties under the Health and Safety at Work Act 1974 (HSWA) and the duties of the various healthcare system regulators. It emerges that there is no clear dividing line between their respective responsibilities and the management of the overlap, which has led to difficulties that are prejudicial to the welfare of patients. There is an urgent need to resolve these issues.

Legislative framework

13.2 The HSWA enacts a general duty on every employer to ensure, so far as is reasonably practicable, the health, safety and welfare of all its employees. The duty extends in particular to:

- The provision and maintenance of plant and systems of work that are, so far as is reasonably practicable, safe and without risks to health;
- The provision of such information, instruction, training and supervision as is necessary to ensure, so far as is reasonably practicable, the health and safety at work of its employees;
- The provision and maintenance of a working environment for its employees that is, so far as is reasonably practicable, safe, without risks to health, and adequate as regards facilities and arrangements for their welfare at work.[1]

13.3 The duty may extend to the prevention of stress-related injuries, for example caused by bullying, but Mr Clive Brookes, who at the time of the Inquiry's hearings, was one of Her Majesty's Inspectors for Health and Safety, suggested this was as yet ill-defined and the understanding of the subject was still being developed.[2]

13.4 This duty is also owed to people who are put at risk by, or in connection with, the activities of persons at work:

> *It shall be the duty of every employer to conduct his undertaking in such a way as to ensure, so far as is reasonably practicable, that persons not in his employment who may be affected thereby are not thereby exposed to risks to their health and safety.*[3]

Breach of this duty is a criminal offence.[4]

13.5 HSE inspectors have a wide range of statutory powers to assist in the performance of their duties, which include the power:

- To enter premises in order to carry into effect any provision of the HSWA;
- To take with them an authorised person;
- To make such examination and investigation as may in any circumstances be necessary;
- To require information to be provided and a declaration of truth signed (it is a criminal offence to fail to provide information when required to do so, but such information if provided is not admissible as evidence in proceedings);
- To require production of records and documents.[5]

1 Health and Safety at Work Act 1974, section 2, www.legislation.gov.uk/ukpga/1974/37/section/2
2 Brookes T109.6–7
3 Health and Safety at Work Act 1974, section 3, www.legislation.gov.uk/ukpga/1974/37/section/3
4 Health and Safety at Work Act 1974, section 33, www.legislation.gov.uk/ukpga/1974/37/section/33
5 Health and Safety at Work Act 1974, section 20, www.legislation.gov.uk/ukpga/1974/37/section/20

13.6 Inspectors have a range of enforcement powers available to them:

- Improvement notices, requiring a person to remedy a contravention of the HSWA;[6]
- Prohibition notices, requiring a person to cease activities that involve the risk of serious personal injury;[7]
- Prosecution for criminal offences under the HSWA,[8] including:
 - A contravention of the general duties under of the HSWA sections 2 or 3 (as referred to at paragraphs 13.2 and 13.3 above);
 - A contravention of a requirement of health and safety regulations made under the HSWA;
 - Obstruction of an inspector in the course of their duties or prevention of a person answering any question to which an inspector requires an answer pursuant to the HSWA.

13.7 Nothing in the HSWA prevents the duties under it applying in a healthcare setting.

Scope of jurisdiction under the Health and Safety at Work Act 1974

13.8 In its terms, the statute has a very wide application. Mr Brookes gave examples of the areas of activity it covers:[9]

- Domestic gas incidents;
- Electricians causing danger in households;
- Central Government premises;
- Military premises;
- Educational establishments;
- Waste sites;
- Hospitals;
- Nursing homes.

13.9 Mr Brookes told the Inquiry that hospitals represented only a very small proportion of the work he does.[10] This must be borne in mind when evaluating the approach of the HSE to healthcare safety issues.

6 Health and Safety at Work Act 1974, section 21, www.legislation.gov.uk/ukpga/1974/37/section/21
7 Health and Safety at Work Act 1974, section 22, www.legislation.gov.uk/ukpga/1974/37/section/22,
8 Health and Safety at Work Act 1974, section 33 www.legislation.gov.uk/ukpga/1974/37/section/33
9 Brookes WS0000050808–809, paras 8–10
10 Brookes T109.36

The Health and Safety Executive's working methods

13.10 Mr Brookes was, at the time of giving evidence, the HSE Principal Inspector in the Midlands Division, whose responsibilities cover the area that includes the Trust. He explained to the Inquiry how the HSE operated in this area.

13.11 A team of inspectors, headed by Mr Brookes at the time of his evidence, worked in offices in Stoke on Trent. They had responsibility for the whole of Staffordshire, except Stoke, and for health and safety enforcement as defined in the Health and Safety (Enforcing Authority) Regulations 1998. They assist local authorities and their environmental health officers in policing lower-risk areas.

13.12 Mr Brookes' team has been of variable size, varying between five and nine inspectors.[11] There are plans for a 35% reduction in funding over the next four years, which resulted in three inspectors taking voluntary redundancy in early 2011. However, at the time of his evidence, the team was as large as it had ever been.[12]

13.13 Inspections in Staffordshire were conducted by the local team on either a proactive or a reactive basis.[13] Proactive inspections were based on a risk assessment of the relevant premises. A computerised model identified and prioritised risks. Typically, Mr Brookes's team has conducted between 10 and 30 proactive inspections each year.[14]

13.14 The Trust's risk rating never rose to a level indicating the need for a proactive inspection during the period 2005 to 2009. However, an inspection occurred in 2007 as a result of a 2006 national directive, and reactive inspections occurred following RIDDOR reports (those submitted under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995) as summarised below.[15] Proactive inspections in Staffordshire included an inspection of 19 nursing homes in conjunction with the Commission for Social Care Inspection (CSCI) resulting in 30% of them receiving enforcement notices.[16] Proactive inspections were also conducted at Burton and South Staffordshire Hospital Trust and South Staffordshire Primary Care Trust.

13.15 In examining the work of the HSE team with regard to the Trust, it must be borne in mind that it formed only a very small part of its workload. Between 2005 and 2009, the team issued between 115 and 175 enforcement notices a year, investigated 40 to 70 formal complaints

11 Brookes WS0000050823–24, para 56
12 Brookes WS0000050808, paras 7–8
13 Brookes WS0000050821, paras 49–50
14 Brookes WS0000050822, paras 51–52
15 Brookes WS0000050822, para 53
16 Brookes WS0000050822–23, para 54

and investigated 30 RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurency Regulations 1995) reportable fatalities.[17]

Health and Safety Executive policy on healthcare-related issues

13.16 The primary duty identified in the HSE national policy with regard to healthcare, formulated in July 2003 and revised in October 2006 and June 2011, is to ensure the health and safety of employed persons in the healthcare sector. The policy gives less priority to enforcement of the section 3 duty where it is deemed clinical judgement is involved, in which case it is thought other regulators are better placed to judge. The national guidance entitled *Priorities for Enforcement of Section 3 of the HSWA 1974* – July 2003 (rev. Oct 2006), in place from October 2006 until 2011, provided that:

> *Priorities for enforcement of section 3 HSWA are set out in HSE's priority programmes and HSE's incident selection criteria. HSE will also give priority to areas where there is a high level of risk involved or in the interests of justice, including those of the injured or bereaved. To enable HSE to meet these priorities, HSE will give less priority to the enforcement of section 3 in the areas below.*
>
> - *Clinical judgements of doctors, dentists etc ...*
>
> *Areas Regulated by Other Authorities and Legislative Regimes*
>
> *Incidents Relating to the Clinical Judgement, and the Training, Systems Of Work Etc To Deliver Those Judgements, Of Doctors, Dentists, etc*
>
> *The Department of Health, and bodies such as the Commission for Health Improvement (CHI) and equivalent bodies in Scotland and Wales, regulates standards of clinical governance, including systems of work, in healthcare. For example, issues such as healthcare associated infection are addressed by CHI and other agencies during visits to healthcare establishments. Similarly, doctors, dentists etc are regulated by other bodies eg General Medical Council (GMC) and other legislation applies to cases of clinical misconduct including manslaughter/culpable homicide or offences under the Medical (Professional Performance) Act 1995, under which the GMC operates.*
>
> *However, it is intended that HSE will continue to deal with the major non-clinical risks to patients such as trips and falls, scalding, electrical safety etc; and with some aspects that apply to both staff and patients alike, such as some healthcare associated infection precautions. Such incidents are normally reported to HSE under RIDDOR. HSE will continue to work with other enforcement agencies in areas where the boundary between "clinical risk management" and "health and safety management" may not always be clear.*[18]

17 Brookes WS0000050809, paras 10–11; WS0000050825, para 61
18 CB/1 WS0000050864

13.17 In 2011, the terms of the guidance were changed but the substance remained the same:

> *HSE does not, in general, investigate matters of clinical judgement or matters related to the quality of care. HSE deal with the major non-clinical risks to patients such as trips and falls, scalding, electrical safety etc; and with some aspects of risks that apply to both staff and patients alike, such as manual handling. Such incidents are normally reported to HSE under RIDDOR, and HSE follow its published incident selection criteria when deciding whether to investigate.*[19]

13.18 Further elaboration on the policy is given in the most recent guidance for the selection of incidents for investigation where they are not required to be reported by regulation (RIDDOR):

> *Fatalities (or serious incidents) not reportable under RIDDOR which should be considered for investigation*
>
> *8. HSE policy recognises that the scope of section 3 is very broad, that section 3 will apply to incidents that are not RIDDOR reportable and that individual decisions must therefore be made on the circumstances of the case. There may therefore be serious incidents that are not RIDDOR reportable but which HSE should decide to consider further.*
>
> *9. In these cases initial enquiries may be necessary and decisions on whether or not to investigate must be endorsed by a Head of Operation. To proceed to investigation, all the following criteria must be met:*
>
> > *a. the incident resulted in death (or where the injuries are so serious that death might have resulted); and*
> >
> > *b. there are, in relation to the circumstances that caused the incident, expected health and safety standards that are defined and are known by the industry/sector in question; and*
> >
> > *c. a clear and likely causal link has been established between a failure to achieve these expected standards and the resulting harm ...*
> >
> > *d. admissible evidence is likely to be available ...*
>
> *Investigation decisions in specific circumstances*
>
> *10. FOD* [the HSE's Field Operations Directorate] *will not usually re-investigate incidents or take over investigations that have been investigated by another (usually more appropriate) body ...*

19 GP/8 WS0000052634

11. FOD does not, in general, investigate matters of clinical judgement or matters related to the provision of care. Other legislation and regulatory bodies deal with these issues. Examples of "provision of care" include situations where poor hydration, poor nutrition or the development of pressure ulcers was the primary cause of death.[20]

13.19 National guidance also restricts investigations in relation to non-employees:

HSE will generally not start to investigate injuries to non-employees, or complaints about risks to non-employees. However, it may be appropriate to do so where initial enquiries, or information from other sources, indicate that a breach of section 3 was the probable cause of, or a significant contributory factor to, the injury or risk, complained of, and:

There was or is a high level of risk or

HSE needs to act/investigate in the interests of justice.[21]

13.20 Mr Brookes said that in cases where the discretion to investigate was exercised, joint working with other agencies was required, and a lack of communication or cooperation could interfere with this.[22]

13.21 It is clear that this restrictive policy derives from an administrative discretion to target resources. The effect of this is effectively to remove the possibility of criminal prosecution arising out of responsibility for such incidents, as neither the Healthcare Commission (HCC), nor now the Care Quality Commission (CQC), had or has powers to prosecute.

13.22 However, this guidance has not prevented the HSE investigating some patient-related incidents. Mr Brookes told the Inquiry that such cases have included patients falling from hoists and windows, accidents due to faulty or badly maintained equipment, burns in baths and from radiators, and exposure to Legionella from water systems. Exceptionally, cases of clinical treatment have also been investigated, where the underlying causes have been unsafe equipment or systems of work.[23]

13.23 He said that: "HSE exists in a morass of overlapping requirements".[24]

13.24 Mr Brookes had not been aware that the HCC did not have powers of prosecution,[25] but this would have made no difference to his approach to the exercise of the HSE's discretion. While it is clear that there was nothing in law to prevent the HSE investigating the concerns at the

20 www.hse.gov.uk/foi/internalops/og/ogprocedures/investigation/index.htm
21 CB/7 WS0000050930
22 Brookes T109.23; T109.90
23 Brookes WS0000050813, para 23
24 Brookes T109.20
25 Brookes T109.28–31

Trust as being pertinent to the safety of its systems of work, it is clear that Mr Brookes would have had no difficulty in exercising discretion against launching an HSE investigation:

> *... our policy seemed clear to me. If it's something physically wrong with the hospital and its equipment, you deal with it. If it's something to do with regulation or behaviours of doctors and nurses, leave it to somebody else. If it's a question of the – the clinical governance, which I understand is the administration of care to a patient through the cycle of being in hospital, then that is a matter for this other body* [the HCC/CQC], *which Parliament has said will deal with the matter. And I had assumed all along that Parliament gave powers out that it saw fit for people to use in circumstances.*[26]

The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR)

13.25 RIDDOR requires employers to report to the HSE any work-related deaths, major injuries or over-three-day injuries, work-related diseases, dangerous occurrences and injuries to people not at work that have arisen in particular circumstances. A hospital's health and safety department will normally be responsible for submitting RIDDOR reports to the HSE. The HSE office in Stoke could receive about 70 RIDDOR reports a week.[27] However, the regulations do not result in many incidents of harm to patients being notified to the HSE.[28]

Relationships with other organisations

Police

13.26 The HSE investigates work-related deaths jointly with the police under a Work-related Deaths Protocol.[29] If an investigation may give rise to a manslaughter charge, the police retain primacy in the investigation, whether or not there may also have been health and safety offences; but primacy transfers to the HSE if the matter might lead only to health and safety charges.[30]

Patient safety incidents involving death or serious harm

13.27 In 2006 a Memorandum of Understanding between the Department of Health (DH), the Association of Chief Police Officers, and the HSE was issued setting out a protocol for liaison and communication between the NHS, police and the HSE in relation to patient safety incidents involving death or serious injury. This set out the limits of the HSE's interest in such matters in vague terms:

26 Brookes T109.30–31
27 Brookes WS0000050813–814, paras 25–26; WS0000050816, para 30
28 Brookes WS0000050816, para 29
29 CB/13 WS0000051202
30 Brookes WS0000050823, para 63

The HSE does not normally seek to apply the HSWA [Health and Safety At Work Act 1974] *to matters of clinical judgement or to the level of provision of care, although it is responsible for enforcing work-related health and safety regulation in a variety of settings including hospitals and nursing homes.*[31]

General Medical Council

13.28 In 2004, the HSE and the General Medical Council (GMC) signed a Memorandum of Understanding.[32] This declared their joint policy intention to pass information to each other to assist in the fulfilment of their duties. Examples were given of:

> *The GMC informing the HSE of investigations that have HSWA implications for either the individual practitioner, service users or employer.*
>
> *HSE informing the GMC of any issues emerging from an investigation or inspection which raised significant concerns or questions about the fitness to practise of an individual registered medical practitioner.*[33]

13.29 The document pointed to a limit in the exercise by the HSE of its powers: "HSE does not, however, in general, seek to apply HSWA to matters of clinical judgement or to the level of provision of care."[34]

13.30 The Memorandum of Understanding stated that it was the GMC's policy intent to disclose information when it considered it to be in the public interest, and referred to cases:

> *... where as a result of the exercise of its statutory functions, the GMC has information that raises issues of health and safety at work in respect of the registered medical practitioner and service users. This might take the form, for example of issues relating to maintenance or medical equipment, systems of work, manual handling of loads, or risks specific to service users such as Legionella, or risks from hot water.*[35]

13.31 Nonetheless, it stated that section 3 of the HSWA applied in relation to not exposing service users to risks to their health and safety. Paragraph 11 of section 3 of the Memorandum of Understanding stated that both the HSE and the GMC had the "policy intent" to share information, which might include the GMC informing the HSE of investigations that had HSWA implications, and the HSE informing the GMC of concerns about the practice of an individual practitioner.

31 CB/14 WS0000051230, para 2.4
32 CB/21 WS0000051389
33 Brookes WS0000050828, para 72; CB/21 WS0000051392, para 11
34 CB/21 WS0000051391, para 4
35 CB/21 WS0000051392, para 12

13.32 For its part, the HSE observed that an inspection, investigation or information received might raise concerns about an individual's fitness to practise, for example: "The information could relate to, but is not restricted to, complaints, deaths, injuries and alleged misconduct resulting in harm, or clinical and performance indicators."[36]

13.33 This Memorandum of Understanding appears not to have resulted in any meaningful exchange of information in Stafford. Mr Brookes told the Inquiry that he was not aware that the Stoke office had ever received a referral from the GMC since his arrival there as Principal Inspector in 2006. He, in turn, had referred one case to the GMC in January 2011, involving a death at the Trust.[37]

13.34 The task for the HSE in deciding whether a matter was likely to fall within the remit of the GMC was arguably much easier than it was for the GMC to decide what information might be of interest to the HSE. While the HSE stated it did not "in general" concern itself with matters of clinical judgement or the provision of care, it clearly retained the discretion to do so, given the wide ambit of the statutory duty under section 3 of the HSWA. It might be thought to be more productive and in the public interest for the GMC to agree to share with the HSE all information relating to the health and safety of service users (and employees) that come into its possession. It would then be for the HSE to exercise its discretion as to what to do with the information.

Concordat

13.35 In June 2004, the HSE signed a concordat with various organisations that inspected, regulated and audited healthcare premises, including the DH, the HCC and the General Medical Council (GMC). This was updated in 2006 and 2009 and is entitled *Working in Partnership, Getting the Best from Inspection, Audit, Review and Regulation of Health and Social Care*.[38]

13.36 The concordat set out an objective for inspecting bodies that said: "Inspections are coordinated with other reviews and collections of data".

13.37 The practice in respect of this objective was defined as follows:

> *Inspecting bodies define their remit, avoiding any inappropriate expansion and explaining in annual plans and reports how they aim to cover that remit. This is communicated to professional, patient and client groups and others, including other inspectorates. The annual plan sets out the inspecting body's annual goals and objectives.*

36 CB/21 WS0000051393, para 15
37 Brookes WS0000050829, para 73
38 Brookes WS0000050827, para 67–68; CB/19 WS0000051330

As inspecting bodies develop their annual plans and reports, they share them with other inspecting bodies to assist the development of coordinated programmes of work, including, where necessary, methodologies of inspection ...

Subject to agreed protocols (for example, regarding the use of confidential personal information), inspecting bodies share relevant information with each other to ensure there is no duplication of collection and that maximum value is obtained from the information collected.[39]

13.38 Mr Brookes told the Inquiry that he understood that the HSE had been informed by the CQC that the concordat was no longer operational. Since the creation of the CQC, the CQC has not signed the concordat and no replacement had been arranged.[40] As of July 2012, the CQC and the HSE have agreed a Memorandum of Understanding.

13.39 The relationship between the HCC and the HSE under the concordat was discussed at a meeting on 11 July 2006 between the HSE Head of Operations for the West Midlands, Mr Nick Ratty, and the HCC Area Manager for the West Midlands, Dr Andrea Gordon, at which Dr Gordon explained the HCC's structure. The main point made was that the HSE should pass on information to the HCC so it could deal with it.[41]

13.40 A note of the meeting recorded:

The bottom line is that they would like the information we have on the H&S performance of healthcare establishments in order to better inform the "health check" which they perform on trusts etc. I encouraged them to use the data on the ... HSE website, of which they were only dimly aware. I was somewhat relieved to hear that they had not been making much use of the concordat website where regulators are asked to place information as to the dates and results of interventions ... the healthcare part of the Public Services sector do not seem to be pushing this very hard. We agreed that getting to know each other better would be helpful (mainly for them) and I agreed I would invite them to a JUMM [joint management meeting] *... Overall, the meeting was constructive and friendly and in order to fulfil the high level commitment to limited joined up working is worth maintaining.*[42]

13.41 The note gives the impression that relations between the organisations were not easy and that Mr Ratty thought that the HCC had more to gain out of the relationship than the HSE.

39 CB/19 WS0000051340
40 Brookes WS0000050828, para 70; T109.84–85; T109.102
41 Brookes T109.88
42 CB/26 WS0000051429

13.42 There was, however, continued contact, as described by Mr Brookes.[43] His attempts to organise joint visits so they could understand each others' method of working were unsuccessful "They don't want to play".[44]

13.43 The HCC did, however, pass on the Trust's annual health check self-declarations. Other than that, the information passed to the HSE was limited. In October 2008, Dr Heather Wood, an Investigation Manager at the HCC, stated in an email that the HCC only informed the HSE of matters relating to infection control or particular health and safety concerns.[45] As the HCC's investigation of the Trust arose primarily out of clinical matters and high mortality rates, the HCC had not specifically informed the HSE of its investigation, although the investigation had been publicly announced. Mr Brookes, respecting her view and not wishing to criticise, pointed out that this was not what it said in the concordat and that even if the HSE was not going to investigate clinical matters, the information was useful to them.[46]

13.44 The HCC did not inform HSE formally of its investigation until January 2009.[47] Mr Brookes told the Inquiry he would have expected the HSE to have been told about this much earlier, in particular as the HSE had previously raised concerns at not being told about the HCC's investigation at Maidstone and Tunbridge Wells.[48] He was not critical of the fact that HSE had not being asked to investigate, but would have expected this sort of information to have been shared under the concordat. Such information might have provided context for the investigation that the HSE was conducting into the case of Mrs Gillian Astbury (see below). However, he understood that the HCC may have had difficulties in weighing up the balance between involving the HSE in a serious case and fears of delays in the process should the HSE decide to investigate.[49]

13.45 Mr Geoffrey Podger, Chief Executive of the HSE, also took a sympathetic view of the lack of communication about the investigation, but for different reasons:

> *I don't myself take the view that this was done maliciously. I think the difficulty was, in many of our dealings with the Healthcare Commission and subsequently CQC, that they clearly very much operated within their own system, which I think they almost perhaps emotionally perceived as self-contained, and I think people doing these investigations were not necessarily as alert as they should have been as to what the wider implications might be of what they were actually finding at any point in time.*[50]

43 Brookes WS0000050880–889, paras 79–90
44 Brookes T109.91
45 HW/2 (4) WS0000074577
46 Brookes T109.104–105
47 Brookes T109.93
48 Brookes WS0000050851, para 155
49 Brookes T109.94–97
50 Podger T111.33–34

13.46 He did not think a belief that the presence of a criminal sanction was inconsistent with obtaining constructive cooperation in remedying deficiencies had played a part (see below).

13.47 However, it appears that, informally, the HCC did tell the HSE of the investigation at a risk summit in November 2008, at which over 40 trusts were reviewed, but that the significance of the information was not appreciated at the time.[51]

Attempts at clarifying responsibilities

The Department of Health

13.48 Mr Podger told the Inquiry that the HSE had found a letter written to the DH by his predecessor in 2003 raising the difficulties caused to the HSE when other regulators undertook investigations in areas where the HSE's powers might be exercisable. His impression was that the position of the HSE had not been considered when the HCC and the CQC were being set up.[52]

The Healthcare Commission

13.49 A meeting was held between the DH, the HSE and the HCC on 7 December 2007 to discuss how they could work together. Ms Anna Walker (Chief Executive of the HCC) noted that there was an overlap in areas of interest and that the HCC did not have powers of prosecution. She noted that there was:

> *... a tension that when HCC come across a serious case that they cannot pursue prosecution even when there is pressure to call people to account. That "tension" in different powers needs to be looked at for the future ...*[53]

13.50 Mr Podger commented at the meeting that there was: "a widely held cultural view that criminal sanctions do not belong in 'clinical circles'". And that the HSE "has to limit itself to worst cases".

13.51 A DH official observed that there was "ministerial ignorance" about the HSE's role and that it had not been mentioned in discussions on strategies to tackle healthcare associated infections.[54]

51 Brookes T109.98–99
52 Podger T111.30
53 GP/14 (2) WS0000052747
54 GP/14 (2) WS0000052748

13.52 Mr Podger told the Inquiry that, in his view, the inhibition of criminal sanctions in clinical cases was not wise:

> *... I know this from my own Department of Health background, there has been a considerable effort to try and address issues of medical accidents, in particular, by trying to, as it were, produce, as it was said earlier, an environment in which people feel unthreatened and, therefore, may be more forthcoming. It had seemed to me, and it still does seem to me, that that objective becomes exaggerated into a view that prosecution has no part to play in the most serious incidents where it would be merited. That was my view in 2006. As you see, it's my view in 2007.*[55]

13.53 He considered that the presence of the possible threat of criminal prosecution only rarely inhibited organisations with which HSE interacted from cooperation in remedying detected deficiencies.[56] He thought that the power to bring a prosecution was useful for two purposes:

> *We would take the view that the powers of prosecution that we exercise are exercised for two purposes. The first is to secure justice, and I must stress that HSE uses its powers of prosecuting sparingly and in the most serious cases, but we do consider that actually issues of justice arise here. Secondly, and it is equally important to us, there is no doubt at all that the possibility of a criminal prosecution actually puts a very useful deterrent force into the overall health and safety system. So we see it both as deterrent and we see it as justice.*[57]

13.54 At this meeting he said he was pointing out that if cooperation was not given in advance, there was a real danger that evidence collected by a healthcare regulator could not be used for a prosecution. He had pointed out that this difficulty had not been theoretical but had arisen in the case of Maidstone and Tunbridge Wells.[58] While there was talk of a workshop on the issue, Mr Podger was unaware of any action to follow up this meeting; certainly there was none that involved the HSE.[59]

13.55 The HSE's experience with the HCC was that its reports were not useful to them:

> *We found that the reports of the Healthcare Commission in which we had been involved, noticeably Maidstone and Stoke Mandeville, seem to us not to be well argued or well corroborated. So we were concerned at the way these reports were done, but I stress again, our concern was in terms of the potential purpose for which we would have liked to have used them, which is not necessarily the purpose for which they were written.*

55 Podger T111.23
56 Podger T111.23–24
57 Podger T111.17
58 Podger T111.27–28
59 Podger T111.31

... our concern was that they would actually produce evidence which would potentially stand up in court, and they did not do this. There were other issues which I know are very sensitive and I know the Inquiry has been involved in before. There is this issue of, from the point of view of prosecution, clearly, if you're talking about a fatality you must be able to identify who the deceased person was. I know the Inquiry has been into the issue of the statistical computations. Clearly, a statistical computation would not form the basis ... for any prosecution case. So we found ... the approach not to meet our standards, though I stress again, they may have taken the view that they were not seeking to meet our standards.[60]

13.56 He explained that his concern was not so much with the content of the report as such, but that for the process of investigation by another agency to be useful to the HSE it needed to be based on evidence that was admissible in a criminal court. He rejected the suggestion that it was not possible for a report to be produced without prejudicing a prosecution or that a prosecution would inevitably delay the progress of another regulator's investigative process.[61]

The House of Commons Health Select Committee

13.57 In a memorandum to the House of Commons Health Select Committee in September 2008 in connection with its inquiry into patient safety, the HSE explained its policy with regard to patient safety incidents, and expressed its concern at the potential for confusion between regulators and among the public in the healthcare field. It observed that it:

Is on occasions drawn into investigating patient safety matters as "the enforcer of last resort" because [other] *bodies do not have appropriate enforcement powers or sanctions. This tendency has become more marked with increasing public expectation for public bodies to be held to account and potentially prosecuted.*

13.58 It complained that:

The current situation can lead to confusion for duty holders, inhibit the establishment of improved management practices and is not necessarily the most effective use of public resources. It is hoped that the establishment of the new Care Quality Commission and its associated provision of enforcement powers can be used to ensure more effective regulation of patient safety ...

60 Podger T111.41–42
61 Podger T111.43–45

While HSE does not seek to intervene proactively in ... areas of clinical risk, our work inevitably overlaps with other bodies inspecting healthcare standards such as the Healthcare Commission. Conversely other bodies' roles overlap with HSE's ... this overlap of legislation and policies can serve to confuse dutyholders, eg an NHS Trust, whose general standards of clinical governance and adequacy of patient service delivery are inspected by one body (Healthcare Commission), but whose failures may be investigated and potentially subject to criminal sanctions by HSE and/or the police. There can also be difficulties in ensuring that the lessons learnt from a variety of investigations are taken forward in a coordinated way which does not leave patient safety at risk.

13.59 The HSE suggested that improved collaborative working with the CQC and inspection and regulation by the most appropriate body would further safeguard patient safety without duplication and undue administrative burdens.[62]

13.60 In its subsequent report, *Patient Safety,* the Health Select Committee did not specifically address the role of the HSE, but it did make the general observation that: "The relationship between bodies responsible for commissioning from, performance managing and regulating NHS service providers is not defined clearly enough."[63]

The Care Quality Commission

13.61 On 20 January 2009, Mr Podger wrote to Dame Barbara Young, the then Chair of the CQC, in connection with a CQC consultation on policy enforcement. His stated aim was to clarify the circumstances in which the HSE might consider it necessary to investigate in the public interest:

HSE sees its role not as a rival to the healthcare regulators but rather as intervening where public interest demands that appropriate powers be used, so that those failing in their duties can be subject to rigorous examination, including the judgement of a public court where appropriate. Our view is that we would undertake investigation of only a few patient safety cases per year and indeed we could not resource a higher level of involvement ...

... recent experiences and accepted precedents as to primacy in such cases tell us that we should be brought in early and then, where appropriate, take over any criminal health and safety investigation.[64]

62 Podger WS (Provisional) HSE0005000061–66
63 *Patient Safety – Sixth Report of Session 2008–09*, (July 2009), House of Commons Health Committee, p 6, www.publications.parliament.uk/pa/cm200809/cmselect/cmhealth/151/151i.pdf
64 GP/12 WS0000052733

13.62 While a reply to the letter was not to be expected, Mr Podger told the Inquiry that the HSE made no more progress on resolution of this issue with the CQC than it had with the HCC:

> *... I must say in fairness to them, they were, throughout the period that I was dealing with them, ... clearly under very heavy pressure on other issues, but although we actually did raise this and I raised this issue personally at every opportunity, we did not make progress, and have not made progress.*[65]

13.63 On 11 August 2009, Mr Podger met Dame Barbara to discuss various issues. Dame Barbara was said to have been keen to reduce the number of inspections by other agencies, including the HSE, to avoid duplication, which, she explained, was meant to produce better coordination.[66] Mr Podger indicated that the HSE would happily agree with this, but that it all depended on agencies informing each other of their intentions.

13.64 On the issue of enforcement, he noted that the "CQC were obviously nervous that we were planning a major move into their territory".[67]

13.65 Both parties, however, agreed that there would be a few cases each year when the HSE's powers of prosecution might be needed.

13.66 On 25 September 2009, a further meeting occurred between CQC and HSE officials to develop a mutual procedure. The HSE representatives indicated that they were content to let the CQC take the lead for all patient and service user-related issues, including issues with bedrails, scalding and falls.[68] Mr Podger expressed to the Inquiry his unhappiness with this line, as it was contrary to his view that there were cases where it would still be appropriate for the HSE to take the lead.[69]

13.67 On 15 February 2009, a joint seminar was held between the CQC, the HSE and the local authority coordinators for regulatory services.[70] Mr Podger told the Inquiry that the HSE was trying to persuade the CQC to lead on patient health and safety issues. The HSE believed, through its experience of RIDDOR, that much could be gained from investigating single incidents, but later learnt that the CQC was not willing to investigate these:[71]

65 Podger T111.38
66 Young T110.108–109
67 GP/18 WS0000052771
68 GP/20 WS0000052775
69 Podger T111.48–49
70 Podger WS0000052460, para 29; GP/16 WS0000052754
71 Podger WS0000052460–461, paras 30–31

THE CHAIRMAN: The CQC argument, if I understood it correctly, is that there are just too many incidents within the National Health Service to make that practical. I expect you might say, well, in your jurisdiction there are hundreds of thousands of incidents and you don't investigate them all?

A. That is exactly the answer I was planning to give, Chair, yes. In fact we have exactly the same problem, but the key then is to have guidance on incident selection, which actually make you concentrate on those which are most serious, and where investigation is likely to be most useful.[72]

13.68 On 19 March 2010, Mr Podger met Ms Cynthia Bower, the then Chief Executive of the CQC. According to Mr Podger, Ms Bower made it clear that the CQC was not willing to assume the HSE's role in relation to health and social care inspections on the grounds that it lacked the expertise, which he thought she was saying against the background of the very significant pressures he perceived the CQC to be under at the time.[73] He felt that this sort of issue would be best solved by all healthcare issues being dealt with by one regulator:

I think the actual cornerstone of my argument is that the healthcare sector would be better regulated if it had one regulator, and I think it follows that whoever then becomes the one regulator will have to acquire expertise in those areas previously discharged by another regulator.[74]

13.69 On 22 November, a further meeting took place between Ms Bower and Mr Podger. Mr Podger's briefing note for the meeting made it clear that the HSE would have to cut back on its activity:

Given HSE's financial settlement ... HSE now needs to make difficult decisions about our priorities. It is likely we will direct most of our activities to high risk activities ... In relation to [prosecutions] *in the past HSE has said that it would pick up a few cases a year, but we may need to review this ... There are ... strong arguments that investigating serious incidents is important to both secure improvement and justice. However HSE is not resourced to investigate the majority of serious and fatal incidents in health and social care so will depend on close collaboration with CQC. Further work is required on this issue.*[75]

13.70 The hope was expressed that this Inquiry would "provide clarity".

72 Podger T111.51
73 Podger T111.51–52
74 Podger T111.52–53
75 GP/31 WS0000052859

13.71 At the meeting itself, Ms Bower is recorded as saying that there was no chance of the CQC taking on further responsibilities given its current workload.[76]

13.72 Throughout this period, Mr Podger said there had been a series of workshops and meetings to try to agree a protocol but as yet no agreement had been reached by the time he gave oral evidence to the Inquiry. His understanding of the position was:

> *... the difficulty is simply that CQC colleagues wish to maintain, as I understand it, the present system, whereby they effectively will do these reports and we shall only learn of them at the end. That is where the difficulty lies. I don't see how we can conclude an agreement on that basis, because clearly we think that's a mistake. Equally clearly they don't.*[77]

The regulatory interface between the Care Quality Commission and the Health and Safety Executive

13.73 As can be seen above, at the time of giving evidence the hopes that the HSE had expressed to Parliament had not been realised. The position reached was that both the HSE and the CQC were telling each other that they did not have the resources to investigate individual cases, raising health and safety issues in the clinical context.[78] This resulted, Mr Podger accepted, in a "stalemate", particularly in relation to the issue of prosecutions of healthcare-related cases:

> *The stalemate, as it were, rests specifically over the issue of prosecutions in the case of – cases which we've discussed at length. My own view is that if it is the view, as it clearly is of the Care Quality Commission, that they do not want and/or are not able to take on other responsibilities for HSE, that is not an unreasonable position for them to maintain ... and indeed they themselves explained the resource constraints that they have. So, I think that's a rather different issue. It was perfectly legitimate for us to raise this proposal. In my view, it is perfectly legitimate for them to say they were unable to go along with it, and they clearly explain why that was, and they were very heavily engaged in other activities with a diminished set of resources. I mean, that is what they say and it is true, as I understand it. So I think, you know, the stalemate of which I would describe is purely over the prosecution issue.*[79]

13.74 He considered that the issue was one that only the Government could resolve.

13.75 He thought that it was unsatisfactory that currently, given the practice and frameworks of each regulator, if a person was killed as a result of the use of a faulty trolley the hospital trust

76 GP/32 WS0000052884
77 Podger T111.60
78 Podger T111.7; Bower T87.115
79 Podger T111.57–58

might be prosecuted, but if the death was due to poor clinical care a prosecution was unlikely.[80] Mr Brookes agreed that unless clarity was introduced there was a danger of the public failing to understand why action was not being taken in particular cases.[81]

13.76 The views of Mr Podger on the advantages of prosecution powers being available have been described above. They were supported by Mr Brookes:

> *I would rather have the suite of powers that I've got, ranging from word of mouth through written communication, through what we would call an incident visit report that we put on somebody's desk, through notices, through seizing defective equipment and taking away and destroying it through to prosecution – I'd rather have my suite of powers than the suites of powers that I've seen in other regulators' hands.*[82]

13.77 In his evidence to the Inquiry Professor Sir Liam Donaldson was strongly against the introduction of a criminal sanction in clinically related cases, in part it seems because of the numbers involved, and in part because it would inhibit candour:

> *... I think it would be ... difficult.* [For example] *you've got your 11 nasogastric tube deaths in 11 hospitals, all the chief executives suspended and expecting an appearance in court, possibly the chairman of the board as well, on corporate manslaughter, and so we've got 11 nasogastric tubes, let's put in, you know, 1,000 deaths from other causes. Where would that end ... at the end of it, would patients be safer as a result of that, or would there just be nobody willing to admit to any mistakes? I think probably the latter.*[83]

13.78 Mr Podger was confident that the HSE could investigate clinical cases if required to do so, but did not currently have the expertise in this area. However, consistently with the HSE's position throughout, he was clear that it was not in the public interest to have "two regulators scrabbling around on the same patch".[84]

The Health and Safety Executive's interaction with the Trust

Prosecutions

13.79 The Trust has been prosecuted twice by the HSE: once for a patient who drowned and once relating to a fall because of a defective window catch.[85]

80 Podger T111.9, 11
81 Brookes T109.210
82 Brookes T109.31
83 Donaldson T122.175
84 Podger T111.7
85 Brookes T109.32

Complaints

13.80 During the period January 2005 to March 2009, no complaints were made to the HSE by any patient group.[86]

Reporting of Injuries, Diseases and Dangerous Occurances Regulations (RIDDOR) reports

13.81 During the period January 2005 to 24 June 2010, the HSE received 107 RIDDOR reports relating to the Trust, of which 61 were accidents involving staff or contractors and 42 involving patients. Most patient injuries reported were falls of elderly patients. An assessment of all these cases in accordance with HSE criteria resulted in a decision not to investigate. A sample of the descriptions of the incidents follows:

- January 2005, a confused elderly patient falling over by his bed, resulting in a fractured right leg;
- July 2006, a patient on Ward 11 was walking down the corridor to the toilet when he lost balance and fell to the floor, resulting in a fractured hip;
- December 2007, a patient was found on the floor by staff following a noise – the floor was wet and the patient had suffered a fractured wrist;
- July 2008, a patient walking to the toilet unassisted slipped, resulting in a fractured hip;
- January 2010, an outpatient fell in the hospital grounds following attendance for clinical investigation and sustained a fractured ankle.[87]

13.82 A number of these incidents involved a fall by elderly, often confused and frail patients who are unlikely to have been receiving appropriate support and care at the time. The numbers of such cases are as shown in Table 13.1.

Table 13.1: Cases of falls reported in RIDDOR reports relating to the Trust 2005–2010

Year	Number of cases
2005	9
2006	2
2007	10
2008	5
2009	4
2010	5

86 Brookes WS0000050825, para 62
87 CB/29 WS0000051454

13.83 A significant number of the cases reported occurred on Wards 10, 11 and 12. Mr Brookes told the Inquiry that before he produced this summary there had not been, and was not normally, any systematic audit or analysis of incidents at the Trust or indeed at any specific organisations.[88] It would appear that this would be the norm in HSE practice.

September 2005 – patient jumping out of window

13.84 On 18 September 2005, a patient, while being treated for acute alcohol withdrawal, accessed a secure area on the first floor, smashed a window and jumped out, sustaining serious injuries. The case was reported to the HSE under RIDDOR.[89] The Trust's internal report on the incident was provided to the HSE in October 2005. It concluded that the incident was rooted in inadequate staff resources to control patient violence; it found that further training in the clinical care protocol dealing with the treatment of acute alcohol withdrawal might be required; it stated that the need to have adequate staff cover required review. The HSE concluded that the issues arising from the incident were mainly clinical, as they related to patient care and medication. Mr Brookes explained: "The only issue of appropriate regulatory interest to the HSE was the potential violence to staff but this was being dealt with as a result of the Trust's investigation."[90]

13.85 Therefore, the only issue that the HSE followed up was that of violence to staff. During a visit by an HSE inspector in October 2005, confirmation was sought that the required actions were being taken. This point was revisited in July 2007 and an improvement notice was issued.[91] However, the HSE policy and the absence of effective coordination with a healthcare regulator ready and willing to examine individual cases meant that any issues relating to the adequacy of the clinical service or the staffing resource went without scrutiny.

October 2005 – patient fall

13.86 On 31 October 2005, an elderly patient with a history of falls was found unconscious on the floor of a ward. The patient subsequently died. The case was reported under RIDDOR. A decision was taken that an investigation was deemed impracticable, presumably because there were no witnesses. In evidence, Mr Brookes referred to this incident as taking place on 28 September 2005, but the HSE report records this as being on 31 October 2005.[92]

13.87 While this may well have been the correct decision at the time given HSE policy, in the hands of a healthcare regulator it might have been expected that some form of inquiry might have been made about the adequacy of supervision arrangements on the ward.

88 Brookes T109.69
89 CB/30 WS0000051497
90 Brookes WS0000050839, para 101
91 Brookes WS0000050836–837, paras 98–101
92 Brookes WS0000050837, para 102; CB/30 WS0000051503

November 2005 – manual handling incident and complaint about bullying

13.88 In November 2005, the HSE received a complaint from a Trust employee concerning a ruptured disc (assumed to be lumbar disc) said to have been sustained in a manual handling incident in the operating theatres. HSE Occupational Health Inspectors made two site visits, as a result of which remedial actions with regard to policy, risk assessments, and training were proposed to the Trust. The Trust later confirmed to the HSE that the required actions had been taken. The same employee wrote again in February 2007, this time expressing a number of concerns about the theatres, including:

- Poor safety equipment and manual handling problems compounded by issues of stress and exhaustion;
- Sickness absence leading to increased stress;
- Stress due to bullying tactics from middle management in the surgical directorate;
- Failure to cancel surgical activity in line with staff shortages, which was forcing staff to work below required standards and placing patients and staff at significant risk.[93]

13.89 The HSE's inspector made a judgement that the manual handling issue in the theatres was the root of the problem being expressed by the complainant, and that if this was tackled properly it would reduce the impact of the other issues. As a result, manual handling was looked at as part of a series of inspections between 23 and 27 July 2007, but these also looked at work stress and violence to staff. An improvement notice relating to manual handling was considered but not issued, as the Trust appeared to be committed to addressing the issue.[94]

13.90 Mr Brookes told the Inquiry that there was no indication during these visits, which included discussions with staff and union officials, of poor clinical conditions.[95] However, perusal of the inspector's report, which was sent to the Trust, does include at least one observation that might have had implications for the standard of care given to patients. It was reported that staff in some departments were experiencing:

> *... particularly high stress levels and felt poorly supported by the organisation. The situation was most evident during discussion with the fracture clinic staff who reported particular concerns relating to the excessive numbers of patients booked into some clinics.*[96]

13.91 No criticism can be made of the diligence with which the HSE inspectors dealt with these complaints, but in hindsight it would have been helpful for information about this sort of incident to be shared with the healthcare regulator who should have been in a better position to assess the significance for patient safety. There is no record that this complaint was shared with the HCC. There were discussions taking place with the HCC at the time but, while it is

93 Brookes WS0000050837–838, paras 104–105, 110–111
94 Brookes WS0000050840–842, paras 113–119
95 Brookes WS0000050842, para 120
96 CB/33 WS0000051617, internal p2

possible this sort of complaint was mentioned at such meetings, there was no system requiring that to occur.[97] Given the concerns about the overlap of functions between organisations and the sharing of information, the implementation of such a system would have been useful. While a system on paper is no substitute for professional judgement, it would serve as a prompt to inspectors to consider on each occasion whether information contained in reports might be useful to another regulator.

2007 – attempts at arranging joint visits of the Trust with the Healthcare Commission

13.92 In early 2007, a lead HSE inspector for the Trust approached the HCC to ask if she could accompany HCC inspectors on a joint visit to the Trust to find out how the HCC went about its work. Several dates were proposed but it proved impossible to organise a joint visit.[98]

13.93 On 17 April 2007, the HSE arranged a meeting with the HCC to discuss all Staffordshire trusts. At the meeting, the HSE informed the HCC of its intention to inspect the Trust (as above) and asked whether this would cause a problem. The HCC indicated they had no issue with this. The HCC also indicated to the HSE that it did not consider the Trust to be a serious concern compared to another trust in the area. According to Mr Brookes, the HSE was left with this impression until February 2009 when it was made aware of the impending HCC investigation.[99]

2008 – complaint of poor hygiene

13.94 On 3 June 2008, the HSE received a complaint about poor hygiene on Ward 10 from a patient. The complaint was that cutlery was not clean and that an open bin by a sink in the ward was being used for soiled incontinence pads. The HSE did follow this up by contacting the Trust and seeking assurances. The matron for Ward 10 was noted to have said that this use of ward bins was in accordance with policy and they were emptied twice a day.[100]

13.95 While this may be viewed as a relatively small incident, and the HSE inspector did follow the matter up in spite of telling the complainant that the complaint about cutlery was not something they could deal with, it could again have been relevant information to feed into a healthcare data analysis such as that now being developed by the CQC.

2009 – cases of two patient fatalities following falls from trolleys

13.96 On 29 April 2009, the death of "Patient B" was reported under RIDDOR. The patient was reported to have fallen from a trolley in A&E. The initial report said the death had been from "natural causes". Mr Brookes visited the Trust to clarify what was intended to be reported and was concerned at what he thought was a dilatory attitude by the Trust. He was eventually

97 Brookes T109.114–116
98 Brookes WS0000050831, para 80
99 Brookes WS0000050831, para 82
100 Brookes WS0000050843–844, para 128

shown the original RIDDOR report form which shows the accident as being the cause of death. He then discovered that for reasons which were not clear, but could not be laid at the door of the Trust, the RIDDOR form had been altered after its receipt by the HSE.[101]

13.97 An investigation into the case was launched and the assistance of the CQC was sought. Mr Brookes was disappointed with the assistance received from the assessor who, he thought, raised more questions than they helped to answer.[102] The CQC official involved, however, pointed out that local assessors did not assess clinical judgements but governance, process, and so on.[103] There appears to have been a lack of mutual understanding of the work undertaken by each party, possibly brought about by a lack of training in each other's work.

13.98 On 12 August 2009, a further RIDDOR report was received concerning another fatality following a fall from a trolley. At a meeting on 9 September, the HSE communicated to the CQC its view that these two deaths amounted to a "trend" that should be investigated. The CQC's reply was that it did not investigate individual cases and did not regard two cases as a "trend".[104]

13.99 The outcome of the inquests into these two deaths effectively removed the cases from the HSE's consideration in accordance with its policy. In the first case, it was confirmed that there was no defect with the trolley or its rails: the death was attributed to a lack of supervision of the deceased. In the second case, the evidence showed that the patient had not fallen off a trolley at all but had climbed off and fallen while walking, which meant that it was not a RIDDOR-reportable incident. The result was that the cases remained without investigation by either the HSE or the CQC.[105]

The case of John Moore Robinson

13.100 On 5 August 2010, the HSE received a complaint from Mr and Mrs Robinson asking it to investigate the death of their son. The facts of the case are considered in *Chapter 2: The Trust* and in the report of the first inquiry. At the time of giving oral evidence Mr Brookes told the Inquiry that no decision had been taken as to whether the HSE should pursue the case.[106] However, Mr Brookes observed that similar considerations applied to those in the case of Mrs Gillian Astbury (described below):

101 Brookes WS0000050844–45, paras 132–133
102 Brookes WS0000050845, para 135
103 Brookes T109.179–180
104 Brookes WS0000050846, paras 137–138
105 Brookes WS0000050848, para 140
106 Brookes T109.166

The situation echoed that of Mrs Astbury, as the HSE policy is normally not to investigate cases of medical negligence. I was concerned that if we did differ from HSE's policy, fully investigate and consider prosecution, there could be a significant number of other cases that would also require review.[107]

The case of Mrs Gillian Astbury

13.101 The facts of this case have been considered in detail in *Chapter 1: Warning signs*. It is a case, however, in which HSE has had a significant involvement.

13.102 On 10 July 2008, the police contacted the HSE with details of the case and invited it to attend a meeting to discuss the case. At that time no RIDDOR report had been received.[108] Mr Brookes was requested by HSE management not to attend the meeting because the deceased had been under medical care and therefore the case fell outside the HSE's remit, a view with which Mr Brookes clearly had sympathy.[109] He told the Inquiry that it would be quite impossible for the HSE, with its limited resources, to investigate all of the thousands of deaths that were reported to it. However, Mr Brookes felt he should attend to maintain a good relationship with the police with whom he had conducted several joint investigations. He also did not feel he could make a judgement on the information he had without a degree of engagement. The meeting was held on 23 July.[110]

13.103 At the meeting, Mr Brookes was shown the Trust's internal report prepared by Mr Stuart Knowles, the then Trust's in-house solicitor. He concluded that this was not a case in which HSE should become involved, as in his view none of the special factors required to trigger involvement in a "clinical" case were present. He emailed his conclusion to the police:

My conclusion is that there appears to be systemic clinical management and individual(s) failure in respect of Gillian Astbury.

There is no doubt that the generality of the Health and Safety at Work Act 1974 section 3(1) applies to the general circumstances of the death of Gillian Astbury. Indeed section 3 of the Act is drawn so widely that it applied to virtually any situation where employment or self employment takes place.

107 Brookes WS0000050848, para 147
108 Brookes T109.128
109 Brookes T109.129–130
110 Brookes T109.132–133

As a consequence of this extraordinary legal inclusiveness, the HSE has had to decide where it should or should not place its resources. In a nutshell, where another regulator has investigative powers or sanctions, and powers to remediate in a given situation, the HSE defers to that organisation ... in this case the Healthcare Commission, formerly the CHI, is regarded by HSE as having parallel powers to HSE in respect of regulating healthcare standards. In addition to this the British Medical Association for doctors, and the Royal College of Nursing for the nursing profession, have, as I understand it, regulatory powers for dealing with clinical malpractice under the Medical (Professional Performance) Act 1995 ...

I have therefore to advise you that as no equipment or structural condition has been identified as a causal factor, as mentioned in the attached policy web page paragraphs above [see this exclusion to the generality of the preceding paragraph]*, then I am sorry to say that I am unable to assist you in my opinion.*[111]

13.104 Mr Brookes' view was based in part on an erroneous understanding of the HCC's powers. He was unaware that it had no powers of prosecution.[112] Rather less significantly, he mistakenly thought that the British Medical Association (BMA) and the Royal College of Nursing (RCN) had regulatory powers, whereas the relevant bodies are the GMC and the Nursing and Midwifery Council (NMC).

13.105 On 28 July 2008, the HCC recorded a call from the HSE informing it about a "manslaughter" case that had been forwarded to the Crown Prosecution Service (CPS). The HCC investigation team was considering the case as part of its evidence in the continuing investigation of the Trust.[113]

13.106 On 6 October 2008, the Crown Prosecutor wrote to Mr Brookes asking him to reconsider his decision not to become involved in the case, having discovered that the HCC had no formal powers of enforcement. The letter made it clear that neither the police nor the CPS had the regulatory knowledge or technical expertise to investigate and prosecute most offences under the HSWA and that they considered HSE input "essential". It was pointed out that if it were decided that there was insufficient evidence of a serious criminal offence, other than a health and safety offence, the case would be referred to the HSE at that stage: "I am sure you will agree that your involvement in the investigation at this stage would make any such consideration of HSWA offences by you a great deal easier."[114]

111 CB/43 WS0000051680
112 Brookes T109.138–139
113 CB/44 WS0000051690
114 CB/45 WS0000051702

13.107 Mr Brookes was persuaded by this to allow the HSE to become involved: "I'm between the devil and the deep blue sea. I've got one policy which says don't get involved, and I've got another policy which says do get involved."[115]

13.108 However, he pointed out that, not only did the police and the CPS lack the relevant technical knowledge, so did he and the HSE.[116] The HSE's involvement was limited to offering assistance to the police, including at one stage obtaining an occupational health report. No steps were taken to undertake any investigation of its own at this stage.

13.109 In December 2008, it was agreed that an approach be made to the HCC to assist in investigating reasonable lines of enquiry in the case, and the HSE offered to make the approach.[117] It was then that the HSE first understood that a full-scale HCC investigation was in progress into the Trust.

13.110 During a discussion that took place on 3 February 2009 about the investigation, the HSE sought early access to a copy of the report before publication to ensure there was nothing in it that could prejudice the police investigation into the case. When it did receive it, the HSE required no amendments to be made.[118]

13.111 In November 2009, Mr Brookes held a meeting with the CQC and Monitor mainly to seek their views on the possible impact on the Trust of a prosecution in the Astbury case (see below).

13.112 In December, the police closed their inquiry and formally passed primacy in the case to the HSE, following a decision by the CPS not to prosecute.

13.113 In advance of the inquest into the death of Mrs Astbury, the HSE obtained a report from occupational health advisers. The report was based solely on Mr Knowles' report and the Trust's action plan. It was therefore of limited authority, firstly because it could not have included a consideration of the original medical records and secondly of any witness evidence that the police may have obtained. Finally, the identity and qualifications of the authors, who have not signed the report, is not disclosed. Therefore, the report would have been of limited use other than as a signpost for further enquiries, and its conclusions cannot be accepted as necessarily correct. Nonetheless, it expressed an opinion that there were areas where the nursing care of Mrs Astbury fell "significantly" below what would be expected, including:

- Failure to ensure an adequate communication system regarding the patient's safety and care over successive shifts;
- Failure to document what nursing care was required;

115 Brookes T109.143
116 Brookes T109.143
117 Brookes WS0000050850, para 153
118 Brookes WS0000050852, para 158

- Failure to provide specific care such as dietary requirements, administration of prescribed drugs to the required standard, regular monitoring of condition, and failure to recognise a deteriorating patient;
- Failure to manage a known condition of diabetes adequately;
- Failure to provide leadership at ward and possibly at trust level;
- Staffing levels;
- Non-compliance with multiple core standards.[119]

13.114 Following a request from the Coroner, the report was disclosed to him on the condition it was only used to assist the Coroner in asking questions, because of its possible use in criminal proceedings.[120] However, Mr Brookes did arrange a meeting with Mrs Astbury's family and their solicitor at which he read out parts of the report.[121]

13.115 The inquest into Mrs Astbury's death took place in September 2010 before a jury, which returned a highly critical narrative verdict (described in *Chapter 1: Warning signs*). Later that month Mrs Astbury's long-term partner, Ronald Street, wrote a closely reasoned letter to Mr Brookes asking whether it was the HSE's intention to launch proceedings. This was followed by a meeting of family members with Mr Brookes, at which he said that this was possibly the most difficult case he had ever had to deal with "because if a successful prosecution was mounted in Gill's case, the HSE was under-resourced to be able to cope with the anticipated demands from other families which might ensue."[122]

13.116 Mr Brookes replied formally to Mr Street on 28 September.[123] He made it clear that the decision as to whether there should be a prosecution had been passed to more senior officials in the HSE. He gave his own opinion that there was evidence on which a case, under section 3 of the HSWA could be mounted. The issue was, he said, whether it was in the public interest to do so. One factor was that the legal costs would have to come out of funds that should go towards patient care.

13.117 Mr Street replied in a letter expressing understandably highly charged criticism of the HSE's approach to both the case of Mrs Astbury and that of the deficiencies reported at the Trust generally.[124]

13.118 On 10 January 2011, the HSE wrote to the Inquiry to say that it had decided to defer the decision to pursue the investigation of the Astbury case further until the conclusion of the Inquiry.[125]

119 CB/49 WS0000051711
120 CB/50 WS0000051725
121 Brookes WS0000050853, paras 161–162
122 Street T12.104
123 CB/59 WS0000051784
124 CB/60 WS0000051781
125 CB/61 WS0000051705

Reaction to the Healthcare Commission's investigation

13.119 On 28 November 2008, two HSE inspectors attended the first West Midlands risk summit at which eight other regulators were represented. At this meeting, reference was made to a "major report into critical pathways", which may have been a reference to the HCC investigation; but it was not understood as such by the inspectors, who had no idea what a "pathway" was.[126] Mr Brookes was unable to recollect the HCC press release announcing the investigation.[127]

13.120 Following the contact with the HCC described above in relation to Mrs Astbury's case, Mr Brookes participated in a discussion with the HCC on 3 February 2009. The HSE made the point that:

> *The HSE needs an intellectually robust justification on relevant evidence to make a decision about whether to proceed or refrain from prosecuting the trust ...*
>
> *Whatever the decision on enforcement action, an overriding aim of HCC and HSE is to secure acceptable standards of care for the population in this Trust's area.*[128]

13.121 Mr Brookes clearly felt on the horns of a dilemma:

> *I did not want the HSE to be seen to try to take over the role of lead regulator for patient safety. I also had to consider the public interest and whether any prosecution was best for the people of Stafford, or whether this would be considered retributive action and it was more appropriate for the HCC to put together a plan for improvement and manage progress against that plan.*[129]

13.122 Following the publication of the HCC's report on the Trust, the HSE had to consider what action, if any, to take in respect of its disclosures. An internal note dated 6 April 2009 to Mr Podger summarised the current HSE position:

> *Our current position is not to investigate further because:*
>
> *i) the language/tone of the Healthcare Commission's report on Mid Staffs does not offer a strong starting point. (That said, the facts as described in the report do raise concerns as outlined below);*
>
> *ii) the* [HCC] *did not involve us/the police in their investigation and consequently we have concerns about admissibility of evidence and that the trail may well have gone "cold";*

126 Brookes WS0000050832, para 84
127 Brookes T109.98–99
128 CB/46 WS0000051705
129 Brookes WS0000050852, para 157

iii) given these concerns, there is limited likelihood of a successful investigation/ prosecution (based on precedent from the Stoke Mandeville and Maidstone cases);

iv) public service improvements have already been achieved (or are in the process of being improved);

Nonetheless, there does appear to be a potential case for further work by HSE for the purpose of "justice"[130]

13.123 Describing the current status of HSE deliberations, the author noted:

> *So far we are "holding off" from an immediate investigation, but our position is far from cast-iron and we could well be pushed to engage further – either through a ministerial or a public call for a more general investigation or as a result of requests to investigate a number of individual cases of patient deaths – each on their own being very hard to refuse.*[131]

13.124 However, the note expressed the fear that there would be evidential difficulties and challenges to resources.

13.125 The note recorded that Head of Patient Safety at the DH (Mr Murray Devine) had contacted the HSE and had said that Ministers would be relieved that the HSE and the police were not currently investigating. He had inquired about the Astbury case, but the HSE had declined to respond on individual cases. Mr Podger was adamant that there had been no question of Ministers seeking to interfere in the HSE's work, and that Mr Devine was doing no more than seeking information, as Mr Devine himself had made clear in an email of 3 August 2010.[132]

13.126 In a question and answer format intended to clarify the HSE's thinking, it was stated that:

- There was general agreement that it was not the HSE's role to investigate the higher than expected mortality rate at the Trust;
- The HCC had not involved the HSE in its investigation and had used "milder language" than in previous reports; it was therefore "reasonable to say publicly" that the HSE did not consider it would be appropriate to conduct a wide-scale health and safety investigation, as the HCC report had already described its comprehensive investigation and had highlighted serious failures;
- The HCC report did suggest that the Trust's management had failed to discharge its duties under section 3 of the HSWA;

130 CB/51 WS0000051727
131 CB/51 WS0000051727
132 Podger T111.86; GP/37 WS0000052908

- If the HSE did decide to investigate, experience suggested that the HCC would not be able to supply it with admissible evidence and would see any HSE investigation as a duplication of effort, as the Trust had been "galvanised" into remedying the issues;
- With regard to the Astbury case:

> *In intervening in such cases at this hospital, HSE will be acting as it would in any other NHS trusts where public interest demands that appropriate powers be used, so that those failing in their duties can be subject to rigorous examination, including the judgement of a public court where appropriate.*
>
> *However, if there have been, as the HC report indicates, many deaths at Mid Staffordshire … then it is unlikely that HSE would be able to resource such investigations without withdrawing significant enforcement effort from other areas or through additional resources.*[133]

13.127 In other words, the more deaths that were alleged to have arisen from a failure to comply with statutory health and safety requirements, the more difficult it was to decide whether or not to investigate because of the resources required.

13.128 Mr Podger in his evidence gave no indication that the central thrust of this note was not broadly reflective of the HSE's thinking.

13.129 Mr Street, whose evidence to the Inquiry was conspicuous for its reasoning and the measured way in which he delivered it, gave his reaction to the HSE's position:

> *I was shocked at some of their attitudes. I took great exception to the fact that they did not consider that the tone of the Healthcare Commission report was sufficiently emotive. If it weren't written down, I would not be able to believe that. And it served to underline the impression that I had been given by Mr Brookes that the Healthcare Commission – the Health and Safety Executive was not – was compromised to carry out its statute obligations …*
>
> *… If the Health and Safety Act and the protection of the Health and Safety Act is going to apply to patients when they are in hospital, either the CQC have got to have stronger powers,* [or] *the Health and Safety Executive's role … has got to be brought more … into the regulation system. I think it is very unsatisfactory at the moment. I don't see that as the system works at the moment patients are adequately protected.*

133 GP/36 WS0000052899

... this is the thing that alarms me. In 76 years, I cannot think of a more despicable, needless waste of life that has occurred at Stafford Hospital if – according to the reports. Now, is it right that just because that situation is so grave that they're not in a position to deal with it? There is something wrong. There is something wrong. Rather than what I called pontificating about whether they were going to investigate the deaths or not it – in my opinion, it demands immediate investigation on the publication of that report.[134]

13.130 On 9 May 2009, Mr Terence Deighton wrote to Mr Brookes asking for clarification about the HSE's position following the HCC report. Mr Brookes replied on 12 May stating that the HCC had primary responsibility for inspecting and regulating healthcare providers and it seemed clear that it had carried out a thorough investigation and made comprehensive recommendations:

I must make it clear that there is no suggestion that the Health and Safety at Work Act etc 1974 does not apply to NHS Trusts, and there is no "grey" area which would exclude healthcare providers, nor individuals, from the scope of the Act as it applies to hospital employees and others, including patients, visitors, etc; however it remains HSE's view that HCC/CQC have primary responsibility for dealing with issues relating to standards of patient care and are best placed to enquire into the type of problems which quite evidently prevailed at Stafford in 2007/8.[135]

13.131 On 17 November 2009, a meeting was held at Mr Brookes' request between himself and a colleague from the HSE, representatives of the CQC and Monitor to explore public interest issues at the Trust and the HCC report findings. Mr Brookes also raised the case of Mrs Astbury, as he wanted to know if a prosecution might distract management from other duties and responsibilities and wanted the opinion of those more knowledgeable about the Trust. The CQC and Monitor, while making it clear that it was for the HSE alone to decide whether to take action, expressed concern about the effect of publicity on management. In particular, they advised that certain issues might impact a prosecution or be impacted on by it. These were:

- The workload of the Board in turning the Trust around and staff morale, which was low;
- It was suggested that the first inquiry, then recently constituted, was a vehicle for wider public examination;
- The CQC and Monitor were already doing much work in their role taking forward issues that the HSE might be concerned about. Steady progress was being made;
- "External organisations might be provoked into a reaction which could divert the Board even further".[136]

134 Street T12.118–120, 124
135 CB/53 WS0000051736–737
136 Brookes WS0000050833–834, paras 88–89; CB/28 WS0000051448; Brookes T109.149–51

13.132 Mr Brookes told the Inquiry that he did not think much had been gained from this meeting and he had not had contact with the CQC or Monitor since.[137]

The liaison agreement between the Health and Safety Executive and the Care Quality Commission

13.133 Since the oral hearings, the HSE and the CQC have concluded their discussions on the improvement of mutual cooperation and signed a liaison agreement in July 2012.[138] Where the agreement applies, the two organisations have agreed among other things to:

- Review the evidence according to the principles of the Work-related Deaths Protocol[139] where relevant;
- Maintain effective mechanisms for liaisons and information sharing;
- Make decisions about regulatory and enforcement action without undue delay while respecting each other's statutory responsibilities;
- Consider from the outset whether there is a role for the other organisation;
- Identify and secure potential evidence and avoid compromising it;
- Determine together whether joint parallel or solo regulatory action will be conducted;
- Through their relevant inspectors, agree what action should be taken and how to coordinate the obtaining of evidence.

13.134 The agreement contains examples of what each organisation is likely to do in particular circumstances. It is made clear in the document that the HSE continues its policy that in general it will not investigate matters relating to clinical judgement or quality of care (see box below).[140]

13.135 The organisations have agreed that there should be a separate information-sharing agreement in relation to routine information about risks in areas of common interest.

137 Brookes WS0000050834, para 89
138 www.hse.gov.uk/aboutus/howwework/framework/mou/cqc-hse-liaison.pdf
139 www.hse.gov.uk/pubns/wrdp1.pdf . CQC is not a signatory to this protocol but has agreed to follow its principles where relevant
140 www.hse.gov.uk/aboutus/howwework/framework/mou/cqc-hse-liaison.pdf, p13

HSE criteria in healthcare-related cases

In general, HSE is only likely to investigate the unexpected death of a service user or serious safety incident resulting in a major injury to a service user where their s3 HSWA policy has been met and:

- The accident or incident is reportable to HSE and falls within HSE's Incident Selection Criteria; or
- The accident or incident is not reportable to HSE but has clearly been caused by well established standards not being achieved and this has arisen from a systemic failure in management systems.

Systemic failures in management systems may include:

- Absence of, or wholly inadequate, arrangements for assessing risks to health and safety;
- Inadequate control of identified, or well recognised health and safety risks; or,
- Inadequate monitoring, or maintenance, of the procedures or equipment needed to control such risks.

'Established standards' in the context of this agreement may include:

- NHS, Department of Health, or other 'safety alerts', or similar warnings, that are widely known across the sector; or,
- HSWA dutyholders' (ie healthcare providers') internal guidance, or well established guidance from others, where this addresses issues that fall within HSE's broader selection criteria; or
- Widely followed, recognised and expected practices for dealing with a particular issue.

HSE will not, in general, investigate where:

- The incident arises from poor clinical judgement (rather than a failure to implement the actions flowing from that judgement);
- The incident is associated with 'standards of care', such as the effectiveness of diagnostic equipment; or the numbers and experience of clinicians;
- The incident is associated with quality of care, such as hydration and nutrition; or
- The incident arose from the disease or illness for which the person was admitted (whether or not that disease was properly diagnosed or treated) – unless the prime cause was inadequate maintenance of, or training in the use of equipment needed to treat the disease or illness; or otherwise falls within the criteria set out above.

Conclusions

Relationships with other bodies

13.136 It is clearly important that relevant information is passed between regulators. There have been difficulties in this regard between the HSE and the HCC, and, at least until the conclusion of the liaison agreement, the CQC. There are clearly challenges for both sides in deciding what it is relevant to pass on. This difficulty is exacerbated if the areas in which each organisation is interested are not clearly defined. As Mr Brookes put it somewhat graphically:

> *Q ... But what is your view, please, on what should or what needs to be agreed between the organisations, in terms of the sharing of information?*
>
> *A. I think it's sharing of information and deciding how we work together, assuming that we continue with the roles that we have. But ... there needs to be clarity on who regulates what and when, and it should be crystal clear to everybody who is doing what, and the simpler it can be, the less black holes there will be between the constellations.*[141]

13.137 Whether or not the CQC is prepared to investigate individual cases, it seems clear that the information contained in RIDDOR reports could supplement that already available to healthcare regulators through the serious untoward incident (SUI) system. Illustrations of such cases are given earlier in this chapter. At the very least, it would provide a check on the consistency of trusts' practice in reporting fatalities and other serious incidents. It would also be desirable for SUI reports involving death or serious injury of patients or employees to be shared with the HSE. However, the HSE is clearly not the right organisation to be focusing on healthcare and this report recommends that the CQC be given additional powers to prosecute offences, as described further below.

Overlap and gaps between Health and Safety Executive and Care Quality Commission regulatory powers

13.138 The scope of the HSWA is extremely wide and covers a vast range of activity. It is applicable in the case of individual injury as well as large-scale systemic failure. As a result, the HSE has responsibilities over virtually every form of workplace and activity. Inevitably, it cannot be expert in all those different areas.

13.139 Its method of working has much to commend it. It operates through inspectors who follow up reports and investigate in a proportionate manner. Their work almost invariably involves site visits and inspections, and face-to-face encounters with responsible managers. They, seek in most cases, to use their powers to achieve practical improvements in safety and reserve their powers of prosecution for the most serious cases and those where they cannot obtain cooperation from the relevant employers and site owners.

141 Brookes T109.102

13.140 Inevitably, it is not possible for a full investigation, still less a prosecution, to be brought in every case where there has been a possible breach of the HSWA or the regulations made under it. Therefore, they have devised a policy seeking to define the factors on which the HSE's discretion to involve itself or not will be based. In this, the HSE is no different from the CPS and the police, which have policies on when to bring proceedings or to allow a matter to be dealt with by a caution.

13.141 The CQC's remit is also wide, but is limited to the healthcare sector. Generally, its powers of prosecution in relation to a breach of the standards defined in the regulations are limited to cases where it has served a warning notice that has not been complied with.[142] The nature of the healthcare regulatory standards is examined in *Chapter 21: Values and standards*. They are not drafted in a manner that would invariably make it immediately apparent to a healthcare provider whether an offence was being committed. This lack of clarity would often mean that a prosecution for breach would be unfair unless there had been a prior warning alerting the provider to the existence of a potentially criminal breach. That would be less likely to be the case if the approach recommended in *Chapter 21: Values and standards* were to be adopted.

13.142 While it is always going to be difficult to devise policies that will satisfy the many conflicting requirements of the public interest, it is clear that the principles by which the HSE has sought to decide whether or not to involve itself in healthcare cases has led to a particularly unsatisfactory situation when placed alongside the CQC's inability to investigate individual cases. This has led to a regulatory gap that needs to be closed.

13.143 The starting point must be that at the moment there is no criminal sanction available, other than that under the HSWA for failures of safety systems to protect patients, unless these follow failure to remedy a breach of certain regulations after issue of a warning notice by the CQC. Only the HSE has power to prosecute for an offence under the HSWA. The policy reasoning behind this may well be that adopted by Professor Sir Liam Donaldson: that it is generally undesirable to bring the criminal law into the clinical arena, as it inhibits openness and improvement. The alternative view is that in appropriate and serious cases it is in the public interest that those responsible for serious breaches of safety requirements should be held to account. Unless such an avenue is available, there is a serious danger that public confidence and trust in the health service will be undermined. No-one sitting through the two inquiries into the Trust can have been left in any doubt about the impact on public confidence of no individual or organisation having been brought to account for the failures in Stafford.

13.144 Given the current gap through which serious cases of safety breaches in a healthcare setting are likely to fall, the approach of the HSE is not calculated to maintain public confidence, even though such an agency is perfectly entitled, and indeed under a duty to take resource

142 See *Chapter 11: Regulation: The Care Quality Commission* for a more detailed description of the CQC's powers.

allocation into account in making decisions on what to investigate.[143] The approach has the appearance of looking for reasons for not taking action rather than starting from a consideration of what is in the public interest. A concentration on the effect of a decision on resources has led to the unacceptable position where the more serious and widespread a failure is, the less likely it is that the HSE will decide to intervene, even where it is apparent that no other regulator is likely to do so.

13.145 Therefore, there is an unsatisfactory gap in the ability of regulators to enforce criminal sanctions in serious cases, in particular those involving death or serious harm to individuals where serious deficiencies in standards are involved. For understandable reasons, given the breadth of its responsibilities, its lack of specialist expertise in healthcare issues, and the existence of regulators apparently better equipped to make judgements on them, the HSE has been reluctant to take a less restrictive approach to healthcare cases. On the other hand, the CQC has relatively limited powers to prosecute. This restriction has, in part, been formed by reservations about the value of criminal enforcement in healthcare.

13.146 While criminal sanctions should be regarded as the last resort, their effective absence in healthcare provision means that an opportunity to focus minds on the importance of applying at least minimum standards, and being able to demonstrate this, is being lost. Just as importantly, when things go badly wrong and serious harm results, the demand and public expectation for accountability is just as strong, if not stronger, in healthcare, as in any other field where obligations of safety are imposed.

13.147 Therefore, there is a strong case for increasing the availability of such sanctions in healthcare and for allowing the CQC the powers to use them. This could be achieved either by extending to the CQC powers of enforcement under the HSWA in the sphere of healthcare provision or by amending the scope of criminal sanction under the healthcare standard-setting regulations.

13.148 It is not for this Inquiry to express a view on what the HSE should decide in the case of Mrs Astbury as it has yet to reach a final decision. However, the factors to be weighed in answering the question of what is in the public interest in a healthcare-related case might be thought to include:

- What proportionate action is best calculated to protect patients (and staff) and maintain confidence in the healthcare system?
- Is the case so serious, either in terms of the breach of safety requirements or the consequences for any victims, that the public interest requires individuals or organisations to be brought to account for their failings?

143 That resources are a legitimate consideration in these circumstances was confirmed by the Administrative Court in 2010: S v HSE [2010] EWHC 560 (Admin), para 7

13.149 In considering both these matters, the HSE should bear in mind the state's obligations under Article 2 of the European Convention on Human Rights (ECHR) to provide a safe system of healthcare and to investigate individual cases of death.

13.150 The European Court of Human Rights in Powell v United Kingdom emphasised that Article 2 of the ECHR imposes an obligation to protect the right to life.[144] The court stated that Article 2, when read in conjunction with the state's duty under Article 1 to "secure to everyone within [its] jurisdiction that rights and freedoms defined in [the] Convention", requires by implication that there should be some form of effective official investigation when individuals have been killed as a result of the use of force by, *inter alia*, agents of the state. The court further confirmed that this is not restricted to cases where the loss of life has occurred as a result of an act of violence, but also when the death has occurred under the care and responsibility of health professionals.

13.151 If consideration of these and other relevant factors indicates that an investigation or prosecution should be brought, but the ability of the HSE to do so is compromised by a lack of resources, it should consider the extent to which the case should take priority over other cases and whether other resources can be made available.

13.152 A perceived lack of expertise within the HSE is not usually regarded as a reason for it not to investigate a case otherwise requiring it. It would be impossible for the agency to possess experts in all fields of activity it has to cover. The answer is of course to obtain external and independent expert advice, as is done day in and day out in the field of healthcare litigation and fitness to practise proceedings.

13.153 While no specific recommendations can be made on what should be the outcome of the HSE's deliberations in cases relating to the Trust, it is clear that there is now considerable urgency required in reaching a conclusion. It is unacceptable that the families of deceased relatives have been left in a state of uncertainty for so long as to whether their demands that individuals or organisations be brought to account will be pursued. At least part of this delay has been because the HSE took no action in the matter while awaiting the outcome of the police investigation. While it is understandable, and perhaps inevitable, that a police inquiry into a possible offence of manslaughter will have taken priority, it is not clear why the HSE and the police could not have been conducting joint inquiries pursuant to the Work-related Deaths Protocol or, to the extent that was not possible, parallel inquiries. The HSE would have been more likely to have taken such a step if its corporate approach had not been so focused on looking for reasons not to intervene. This is not intended to be a personal criticism of Mr Brookes, the relevant lead inspector, who was bound by policy.

144 Powell v UK ECHR [4 May 2000] 45305/99, [2000] 30 EHRR CD 152, [2000] ECHR 703

13.154 Whatever is decided about the Mrs Gillian Astbury case, the regulatory gap needs to be closed as a matter of urgency. It should be recognised that there are cases that are so serious that criminal sanction is required, even where the facts fall short of establishing a charge of individual or corporate manslaughter. There will be cases, even where they involve clinical judgement, that expose serious system failings, and grossly incompetent management and procedures, not confined to issues of defective equipment.

13.155 The argument that the existence of a criminal sanction inhibits candour and cooperation is not persuasive. Such sanctions have not prevented improvements in other fields of activity, particularly where they are only used proportionately and in cases where improvements are not made, or the deficiencies are particularly serious. It is likely that nothing will focus the minds of a board or trust leaders more on avoiding serious breaches of safety requirements than the possibility of prosecution. Clearly, it should be a last resort, sparingly used, but it undoubtedly has its place in maintaining public confidence in the system and preserving proper standards of service.

13.156 The HSE is clearly not the right organisation to be focusing on healthcare. Either the CQC should be given power to prosecute HSWA offences or a new offence containing comparable provisions should be created under which the CQC has power to launch a prosecution.

13.157 The CQC should review its policy of not investigating individual cases. It is depriving itself of a very real opportunity to detect serious failings in the system and the chance to cause them to be remedied. The Gillian Astbury case, if investigated earlier by a healthcare regulator, would have brought to light many of the deficiencies identified by the HCC report. Obviously, it is not practical to investigate all complaints or all incidents. There are too many, and the majority are best dealt with by the provider trusts through the complaints and incident investigation processes. Nonetheless, the CQC should be able to review complaints and incident reports, and have the resources to launch an investigation comparable to the type of process currently undertaken by HSE inspectors, where serious non-compliance with relevant standards is suggested, even in relation to the case involving a single incident affecting one individual. This is not to suggest that the CQC should be charged with investigating, still less resolving, complaints as a whole.

Summary of recommendations

Recommendation 87

The Health and Safety Executive is clearly not the right organisation to be focusing on healthcare. Either the Care Quality Commission should be given power to prosecute 1974 Act offences or a new offence containing comparable provisions should be created under which the Care Quality Commission has power to launch a prosecution.

Recommendation 88

The information contained in reports for the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations should be made available to healthcare regulators through the serious untoward incident system in order to provide a check on the consistency of trusts' practice in reporting fatalities and other serious incidents.

Recommendation 89

Reports on serious untoward incidents involving death of or serious injury to patients or employees should be shared with the Health and Safety Executive.

Recommendation 90

In order to determine whether a case is so serious, either in terms of the breach of safety requirements or the consequences for any victims, that the public interest requires individuals or organisations to be brought to account for their failings, the Health and Safety Executive should obtain expert advice, as is done in the field of healthcare litigation and fitness to practise proceedings.

Chapter 14
Certification and inquests relating to hospital deaths

Key themes

- There is often tension and misunderstanding between doctors and coroners' offices over the certification of the cause of death.
- Improvements are required in the accuracy of the cause of death certified and the identification of cases to be referred to the coroner.
- Guidance is required on the appointment of assistant deputy coroners.
- A consistent practice is required for approaching families and responsible doctors after a hospital death and establishing if they have concerns relevant to the issue of whether an inquest should be held.
- The practice and procedure concerning the distribution by hospital trusts of evidence and information to coroners require review and improvement.
- The involvement of bereaved families in the coronial experience has been variable.
- More effective use can be made of Rule 43 reports.

Introduction

14.1 This Inquiry is not an occasion for a wholesale review of the coronial system or the process for the certification of death, both having recently been the subject of legislative reform.[1] However, the events at Stafford between 2005 and 2009 have exposed concerns which need to be addressed.

14.2 The Inquiry heard evidence suggesting that the cause(s) of death included in certificates relating to deaths occurring at the Trust were often inaccurate or incomplete. Such deficiencies are unacceptable because they mislead the family of the deceased and the coroner. They are also a significant impediment to the reliability of mortality statistics, which, for all the

1 Coroners and Justice Act 2009: www.legislation.gov.uk/ukpga/2009/25/contents

difficulties of interpretation are, and will remain, an important indicator of the effectiveness of care and treatment.

14.3 The Inquiry also heard a number of families' experiences of inquests into the deaths of their loved ones. The evidence around these inquests suggests that the process is not as effective as it might be in meeting either the public interest or the needs of interested parties.

14.4 One feature of the coronial jurisdiction examined at the Inquiry has been the use of Rule 43 letters or reports. Again, they may not have been deployed to full effect in hospital cases.

14.5 Significant changes have occurred in the coronial court system since the events under review, including the appointment of a Chief Coroner and the creation of the new post of Independent Medical Examiner (IME). The concerns raised by the Stafford experience will have to be considered in the context of these changes.

Certification of the cause of death

14.6 Under the Births and Deaths Registration Act 1953 (1953 Act), a Medical Certificate of Cause of Death (MCCD) is required before a death can be formally registered. When filling in the MCCD, a doctor must state:

- The name and place of death of the deceased;
- The date of the death;
- The deceased's age as stated to the doctor;
- The date on which the doctor last saw the deceased alive.

14.7 The doctor must then indicate whether the cause of death was deduced with the aid of a post-mortem examination and, if not, whether one will be held, or whether the death has been reported to the coroner. The doctor will state whether the deceased was attended to by him/her or another medical practitioner, or no practitioner. The cause of death then needs to be outlined according to World Health Organization guidelines.[2]

14.8 Under section 22 of the 1953 Act, when any person has been attended to by a registered medical practitioner (the attending doctor), that practitioner shall sign the MCCD identifying the cause of death "to the best of his knowledge and belief". When cause of death is unknown, the coroner should be notified for a post-mortem or inquiry to be held.[3]

2 *Third Report – Death certification and the investigation of deaths by coroners* (14 July 2003), chapter 5, paras 5.7–5.13. www.shipman-inquiry.org.uk/tr_page.asp?id=107
3 Coroners Act 1988, sections 8 and 19

14.9 Therefore, an attending doctor's decision as to whether he/she is able to certify a cause of death may determine whether or not a coroner decides to direct the performance of a coroner's post-mortem. This may in turn cause a delay in the burial or cremation of the deceased.

14.10 As described by Dame Janet Smith in the Shipman Inquiry,[4] the MCCD serves three purposes:

1. To provide a record for administrative purposes;
2. To provide an accurate record of the cause of death. She stated that this is needed not only for research and allocation of NHS resources, but in addition for the benefit of the family of the deceased and those who cared for him/her;
3. To provide a safeguard against the concealment of homicide and neglect leading to death by providing a deterrent and a means of detection should they occur.

14.11 Dame Janet concluded that the third purpose was not well served by the system, but she was persuaded that it worked reasonably well for the second.[5] The evidence before the present Inquiry has been less reassuring and it appears that this concern is not restricted to the Trust.

Cremations

14.12 It is worthy of note at this point that there are further checks and balances in place for cremation cases after the MCCD is prepared. This is of course because once a body has been cremated, there is no possibility of further examination if questions arise about the death. The process is governed by the Cremation (England and Wales) Regulations 2008. This procedure is taken extremely seriously; criminal and General Medical Council (GMC) proceedings have been successfully brought against medical practitioners who have falsely completed the forms.[6]

14.13 The main difference with a cremation is that there are two further forms that may be completed: the medical certificate (Cremation 4) and the confirmatory medical certificate (Cremation 5). Further, the cremation must be approved by a medical referee (a registered medical practitioner of at least five years' standing with the character, experience and qualifications for the role).[7] The applicant for cremation (normally a relative or executor of the deceased) has the right to inspect both forms.[8] After this, if satisfied, the referee will confirm his approval on form Cremation 10, authorising cremation.

4 *Third Report – Death certification and the investigation of deaths by coroners* (14 July 2003) www.shipman-inquiry.org.uk/thirdreport.asp
5 *Third Report – Death certification and the investigation of deaths by coroners (*14 July 2003) chapter 5, para 5.20 www.shipman-inquiry.org.uk/tr_page.asp?id=107
6 *The Cremation (England and Wales) Regulations 2008: Guidance to medical practitioners completing forms Cremation 4 and 5,* (20 February 2012) Ministry of Justice, page 9, para 10, www.justice.gov.uk/downloads/burials-and-coroners/cremations/cremation-doctors-guidance.pdf
7 The Cremation (England and Wales) Regulations 2008, Reg 7
8 The Cremation (England and Wales) Regulations 2008, Regs 15 and 22

14.14 Cremation 4 is filled in by a medical practitioner, normally the attending doctor (the Cremation 4 practitioner). It requires him to set out the deceased's medical history as fully as he can and to identify, as clearly as he can, the cause of death. This includes the main cause and any further underlying illnesses the deceased may have been suffering from.[9]

14.15 Regulation 17 of the 2008 regulations provides for Cremation 5 to be completed by a fully registered medical practitioner of at least five years' standing. The aim is to corroborate the cause of death as set out in Cremation 4. The Cremation 5 practitioner should not be a relative of the deceased, or a relative, partner or colleague in the same practice or clinical team of the Cremation 4 practitioner.[10]

14.16 Form Cremation 5 may not be required if:

- The death occurred in hospital and the deceased was an inpatient there;
- A post-mortem has been carried out or supervised by a registered medical practitioner of at least five years' standing (who is not a relative of the deceased, or a relative, partner or colleague in the same practice or clinical team of the medical practitioner giving form Cremation 4);
- The Cremation 4 practitioner is fully aware of the post-mortem.[11]

14.17 If the medical practitioner performing the post-mortem is not independent of the Cremation 4 practitioner, or the Cremation 4 practitioner is not aware of the results of the post-mortem, then the medical referee will require form Cremation 5 to be filled in, which could cause delay to the funeral and additional cost to the applicant.[12]

14.18 If the medical referee is not satisfied that the fact and cause of death of the deceased have been definitively ascertained, or suspects that the death may have been violent or unnatural, then he can make or request a post-mortem.[13] Then if that post-mortem does not resolve the above concerns, a cremation cannot be authorised without an inquest being opened and a certificate of the coroner being issued.[14]

14.19 The forms are then sent to a medical referee who will authorise the cremation. Referees are unable to do so unless the relevant forms have been properly completed in accordance with the Cremation (England and Wales) Regulations 2008.

9 The Cremation (England and Wales) Regulations 2008, Reg 17(1)
10 The Cremation (England and Wales) Regulations 2008, Reg 17(2)
11 The Cremation (England and Wales) Regulations 2008, Reg 17(3)
12 *The Cremation (England and Wales) Regulations 2008: Guidance to medical practitioners completing forms Cremation 4 and 5,* (20 February 2012) Ministry of Justice, page 13, para 29
Available at: www.justice.gov.uk/downloads/burials-and-coroners/cremations/cremation-doctors-guidance.pdf
13 The Cremation (England and Wales) Regulations 2008, Reg 24(2)
14 The Cremation (England and Wales) Regulations 2008, Regs 24(4) and 24(5)

14.20 Under Regulation 16, no cremation can take place unless either a MCCD has been issued or, if an inquiry or post-mortem has been carried out on the deceased, the hospital trust or relevant authority with possession of the deceased can confirm that there is no further need for inquiry or examination of the body.

Pressure on doctors to certify a cause of death

14.21 Dr Valerie Suarez, the Trust's former Medical Director, was a Consultant Pathologist and therefore had a degree of familiarity with the coronial system in the area. She told the Inquiry that she had developed concerns following reports being made to her that pressure was being applied to doctors to enter a cause of death on the MCCD, even though there was uncertainty. The correct procedure where there is medical uncertainly is that this should be reported to the coroner's officer and that the coroner should make further inquiries, possibly including the holding of an inquest.

14.22 Dr Suarez explained the reason for her concern:

> *I think from the coroner and the coroner's officer's point of view, if the death was regarded as natural, then from their ... point of view they didn't need to take it on as a coroner's case, in their view, I suspect, because the cause of death was natural and, therefore, didn't require further investigation. My point is that a death certificate should reflect as accurately as possible the cause of death, because so much rides on it, in terms of education and policy, direction, as well as for the – obviously, for the individual and relatives concerned. So I'm coming at it from a slightly different angle.*[15]

14.23 More direct evidence of the nature of contacts between the coroner's officers and junior doctors who were preparing and signing certificates came from Kath Fox, the Trust's Bereavement Officer and UNISON representative; she witnessed telephone conversations between them, as doctors would prepare certificates in her office. Although she could only hear one side of the conversation, Ms Fox gained the impression that, on occasion, doctors were being put under pressure to record a cause of death even though they were uncertain about it. She told the Inquiry:

> *... The coroner's officer had a heart of gold and believed that people should die with dignity. Many families would not have wanted their relative to be put through a post-mortem, and a decision to put a certain cause of death in the doctor's medical opinion could save the family that trauma.*[16]

14.24 On one occasion, she said, she saw a junior doctor apparently reduced to tears after a conversation with the coroner's officer.

15 Suarez T59.85
16 Kath Fox WS0000004512, paras 72–73

14.25 Kath Fox said she had raised her concerns about this pressure with Dr Suarez. Dr Suarez told the Inquiry that she, in turn, raised this matter with HM Coroner for Staffordshire (South), Andrew Haigh. She said that Mr Haigh had responded, stating that he had full confidence in his officers. Given that response, Dr Suarez said that she felt she could not take the matter further, particularly because, as is described below, she discovered the need for an improvement of practice within the Trust in any event.[17]

14.26 Mr Haigh (in evidence) denied that either he or his officers would ever put pressure on a doctor to: "try and make something natural that was unnatural. That's – that's just not something that we would do."[18]

14.27 However, there were circumstances in which a doctor's professed inability to identify the cause of death might be challenged:

> *... Where someone has been in hospital for some time, several days, a week or more, and a junior doctor comes along and says "Sorry, Mr Coroner, or coroner's officer, I'm unable to give an adequate cause of death in this matter". And there are two immediate concerns from me, or my coroner's officer, about this. The first is "Well, what on earth has been going on for the last week or so? Surely you must have some idea as to what this – what is wrong with this patient when they've been in hospital for some time". And the second concern is that the consultant ... knows the problems about arranging a hospital post-mortem and is actually thinking "Well, wouldn't it be nice to have a coroner's post-mortem in this case so I can get a better understanding as to what has actually gone on with this person?" So those are my concerns. And in those circumstances, I will instruct my coroner's officer to say "Right, check it, press it, see if you can get an accurate – a proper cause of death from the treating doctor".*[19]

14.28 He said that quite often in such cases after having a word with the consultant to make his point, he would end up ordering a coroner's post-mortem in any event:

> *At least I've made the marker that, you know, I'm not going to direct unnecessary post-mortems simply for the sake of doctors wanting to know a bit more about what has been going on with one of their patients.*[20]

14.29 He did not consider that it was unjustifiable to expect doctors who had treated a patient over a period generally to know the cause of death:

17 Suarez T59.89
18 Haigh T48.25
19 Haigh T48.26–27
20 Haigh T48.27

I am keen for a doctor to be able to issue a medical certificate, if they can. But this isn't by way of putting undue pressure on the doctors in inappropriate cases. I think what I would say is that doctors should be aware of what someone is being treated for and, hopefully, you know, should know what someone has died from. And, therefore, doctors may be asked to do – check that or clarify that. Now, I'm not saying that – that I am technically putting pressures on doctors to issue medical certificates. I think what I'm saying here is that doctors should be properly informed or have a proper knowledge of that patient before making a final decision as to whether they are actually in a position to issue a medical certificate or not.

THE CHAIRMAN: So, basically, you're saying you can put pressure on them to do the work?

A. Yes.[21]

Inaccurate certification of the cause of death

14.30 Kath Fox told the Inquiry that she had concerns that death certification was not always accurate. On occasion, she found that the cause of death on the MCCD did not match the information in the medical records, or that a case had not been referred to the coroner when it ought to have been.[22]

14.31 Certification of death at the Trust was found to be deficient. An independent review of death certification at the Trust was commissioned in 2008 by the Trust's Mortality Group set up by Dr Suarez. It made a number of concerning findings:

- In 22% of just over 200 cases occurring between April and June 2008, there was a significant difference in the cause of death recorded in the MCCD and that recorded in corresponding medical records;
- There was a further number of cases in which the cause of death was unknown or unclear after review of the notes;
- 27% of cases should have been referred to the coroner and accepted as coroner's cases, but had not been.[23]

14.32 The Mortality Group recommended that, whenever possible, the consultant in charge should be responsible for issuing the MCCD or be consulted. This recommendation was sent to all consultants at the Trust by Dr Suarez on 3 September 2008.[24] Dr Suarez pointed out the review had not involved interviews with doctors who signed the certificates and that such interviews might have provided an explanation not evident from the records. However, she accepted that the broad thrust of the report was correct.[25] Dr Suarez considered that the cause of the

21 Haigh T48.28–29
22 Fox T43.153
23 Suarez VS/25 WS0000012734
24 Suarez VS/25 WS0000012734; Suarez T59.87
25 Suarez T59.86–87

problem was due, in part, to a lack of training of junior doctors who may have been wrongly delegated the task of completing the MCCDs by consultants without closer inspection, and in part to the difficulty of the process of identifying a cause of death in cases where the deceased had suffered from multiple problems.[26]

14.33 A subsequent audit suggested that the situation had not improved and further training was carried out. Dr Suarez did not think the results of this review disclosed a state of affairs very different from what could be discovered in other hospitals.[27]

14.34 Until being shown evidence of this survey by the Inquiry, Mr Haigh had not been aware of it or its findings. This would have caused him concern if the implication of the results was that cases which should have been referred to him had not been. However, he pointed out that the mere fact that an erroneous cause of death had been entered on the MCCD did not mean necessarily that the case involved a possible unnatural death. He also suggested that there was national evidence available indicating a high proportion of erroneous causes of death being recorded.[28]

14.35 Where the coroner discovers that a cause of death has been incorrectly certified, it appears that there are no consequences which flow from that other than the possibility of an informal "telling off" by either the coroner's officer or the coroner.[29]

Independent medical examiners

14.36 The Coroners and Justice Act 2009 contains prospective provisions which would have required primary care trusts (PCTs) to appoint Independent Medical Examiners (IMEs). Under the Health and Social Care Act 2012, this responsibility will now be exercised by local authorities who are also responsible for the appointment of coroners.[30] Although required to undertake an independent judgement, IMEs may be practising clinicians who are employed part of the time by the very trusts whose patients' deaths they are instructed to scrutinise.[31]

14.37 Dr Alan Fletcher, an IME as part of a pilot programme in Sheffield, had some reservations as to how independence was to be maintained in these circumstances:

> *I don't think it will ever be practical to have totally separate medical examiners working, for example, at a neighbouring hospital to review the* [neighbouring] *hospital ... I think geography of the service will prevent that in its entirety.*

26 Suarez T59.87–88
27 Suarez WS0000012511 para 134
28 Haigh T48.23
29 Haigh T48.19–20
30 Letter of Secretary of State, 11 April 2012 www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_133693.pdf
31 Fletcher T37.98

THE CHAIRMAN: And it's not intended it be full-time role for anyone, I suppose?

A. No, those sessions which a medical examiner devotes to doing that work are appointed to totally separately and have no configuration within the trust. But when I've asked this question I don't think there is a completely clear answer, but as far as the intention goes, that independence is of critical importance and every effort should be made locally to maintain that.[32]

14.38 There is also intended to be a National Medical Examiner who will issue guidance on the performance of an IME role.[33] At the time of the hearings, the Inquiry was told that the appointment of a "shadow" National Medical Examiner was imminent.[34] Since then the Secretary of State for Health has announced that the starting date for this scheme has been put back until April 2014.[35]

14.39 The precise function of IMEs is to be defined in regulations, but the Inquiry heard from Dr Fletcher, who is piloting the introduction of the scheme. He told the Inquiry that the IME has two functions: to ensure that cases which should be reported to the coroner are in fact reported and to ensure that medical certificates of the cause of death are as accurate as possible.[36] IMEs will be appointed locally and given responsibility for an area and will therefore be able to develop an overview. They will be expected to have regard to relevant standards and to report any concerns they uncover.

14.40 Dr Fletcher told the Inquiry of his pilot project in Sheffield. To the date of his evidence, he had reviewed about 5,000 deaths, mostly occurring in hospital, and together with colleagues about 90% of all hospital deaths had been reviewed.[37] He is able to review the case before a cause of death is proposed by the certifying doctor. He focuses on the final illness but also takes account of previous admissions and other clinical information. He is able to contact clinical staff if necessary. The average time he takes over a case is 20 minutes. He then discusses the case with the certifying doctor with one of two outcomes: an agreed cause of death to be entered on the MCCD, or a referral to the coroner. In each case, he contacts the relatives of the deceased to discover whether they have any concerns about the way the deceased passed away or about the care received.[38] This, which he described as the "Shipman question", is to be a legal requirement. Clinical governance concerns, even if not resulting in a referral to the coroner, will be reported to the provider's medical director and in lay terms to relatives of the deceased. Dr Fletcher expressed confidence that the number of correct referral decisions has improved because of this approach; as has the accuracy of certificates.

32 Fletcher T37.98
33 Coroners and Justice Act 2009, sections 19–21
34 Fletcher T37.95
35 Letter of Secretary of State, 11 April 2012 www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_133693.pdf
36 Fletcher WS0000002953, para 2.2
37 Fletcher WS0000002954–5, para 3.1; Fletcher T37.75–76
38 Fletcher WS0000002956, para 3.6–3.7

14.41 Dr Fletcher told the Inquiry that practice varied with regard to whether cases involving hospital-acquired infections were reported to the coroner, as there was no legal requirement to do this. Coroners have no power to require particular categories of case to be reported to them.[39] However, he considered that the IME system would improve the position:

> *... the medical examiner system has enabled a much more consistent appreciation of what makes a death unnatural, in its broadest possible terms. And if a healthcare-associated infection is considered unnatural in those circumstances, then there will be a duty on the reporting doctor to report – attending doctor to report to the coroner, which currently doesn't exist in law.*[40]

14.42 Another advantage of IMEs is that they would be more likely to pick up the background history of a serious untoward incident (SUI) and its potential connection with a death than an inexperienced junior doctor new to the case.[41] However, it is not Dr Fletcher's practice to look for SUI reports, as he would expect some reference to be found in the records.[42] He found that, after some initial scepticism, the contribution made by IMEs has been welcomed by clinicians who have seen it in action.[43]

14.43 Dr Fletcher considered that it would be helpful for each local area to have a senior clinician appointed as a coordinator of the IME service, who had the time to take an overview of the findings being made so as to look for patterns, to peer review and support colleagues' work, and to follow up on concerns that have been raised.[44] He agreed that IMEs could have a role in offering advice to the coroner on clinical matters which might not be within the expertise of the pathologist reporting to him, although this would not derogate from the need for expert evidence in some cases.[45]

39 Fletcher T37.82–83
40 Fletcher T37.84
41 Fletcher T37.85–87
42 Fletcher T37.100–101
43 Fletcher T37.93–94
44 Fletcher T37.105–106
45 Fletcher T37.112

14.44 Dr Fletcher is confident that the IME service has been favourably received by bereaved families:

> *I can say, with no doubt, that the service that we provide has been welcomed by the families of the bereaved. We've verified that independently by anonymised questionnaire study, because all of this was finding our way and establishing the pilot and we wanted to know that our contact with the bereaved was not regarded as intrusive or unnecessary. Far from it, the responses have been overwhelmingly positive. How reassuring it was, for example, to be – to be told "I'm glad that somebody else is looking at every case. That's a real comfort to us". And "Thank you for listening to my concerns and explaining things".*[46]

Appointment of assistant deputy coroners

14.45 Coroners on occasion need assistance to cope with their workload and for that purpose they have the power to appoint assistant deputy coroners, but this is not to be confused with the duty under the same section of the Coroners Act 1988 to appoint a deputy coroner.[47] There are no requirements in the Coroners Act for the procedure to be followed for such an appointment. Appointment of an assistant deputy can be revoked by the coroner at any time. The powers of an assistant deputy are those of the deputy coroner where the latter is unable to act, and when sitting on inquests, the powers are the same as those of the coroner.[48] In Stafford, appointments were required to be approved by the County Council Chair, although, said Mr Haigh:

> *... it tends to be just a checking – a tick box exercise or equivalent. So the appointment is by me but strictly it is approved by the chairman of the county council.*[49]

14.46 Appointments of coroners themselves were the responsibility of local authorities, although in the case of designated metropolitan areas appointments required the approval of the Secretary of State for Justice.[50]

14.47 The situation will change when the Coroners and Justice Act 2009 is implemented. Then the number of assistant deputy coroners for an area will have to be specified by the Lord Chancellor and any appointments will require his consent.[51]

46 Fletcher T37.121–122
47 Coroners Act 1988, section 4
48 Coroners Act 1988, section 5
49 Haigh T48.160
50 Coroners Act 1988, section 1
51 Coroners and Justice Act 2009, Sched 3 para 2

14.48 Mr Stuart Knowles was appointed by Mr Haigh as an Assistant Deputy Coroner while also employed as the Trust's in-house solicitor. There is no question of either Mr Haigh or Mr Knowles acting improperly. Mr Knowles told the Inquiry:

> *... since I was appointed as an Assistant Deputy Coroner for South Staffordshire I have never placed myself in a position of conflict. I took the decision (in conjunction with the Coroner) never to hear cases involving care from the NHS at all ...*[52]

14.49 However, Mr Knowles's appointment has given rise to the Inquiry considering the challenges potentially thrown up by such an appointment.

14.50 It appears from Mr Haigh's evidence that while Mr Knowles did not sit in any inquests involving the Trust, Mr Haigh could not say whether he would ever have been involved in handling correspondence from the Trust, even though that was unlikely:

> *On rare occasions he might be asked to deal with paperwork emanating from the trust, and in those cases what would happen is that he or the other assistant deputy would be extremely cautious about signing that paperwork, and if they were unhappy about signing it, not sign it.*[53]

14.51 It was also possible, albeit rare, for an assistant deputy coroner to be called upon to give advice about MCCDs.[54]

14.52 As Solicitor for the Trust, Mr Knowles had to have dealings with the coroner and his office. Mr Haigh did accept that this might have created a perception of too close a relationship with the Trust, but, he said: "the important factor is for me to maintain my independence, which I have done."[55]

14.53 Mr Knowles compared his appointment with that of a Crown Court Recorder who presides over advocates from his/her own chambers.[56] He considered that in both cases the individuals had to be trusted to behave appropriately.

Decisions on whether an inquest should be held

14.54 Under the Coroners Act 1988 as it was then enacted, an inquest had to be held where the coroner had cause to suspect that the deceased:

52 Knowles WS0000074653, para 58; Knowles T131.111
53 Haigh T48.158
54 Haigh T48.158–159
55 Haigh T48.159
56 Knowles T131.114–116

(a) Had died a violent or an unnatural death; or
(b) Had died a sudden death of which the cause was unknown; or
(c) Had died while in custody.[57]

14.55 A concern that death may have been caused or significantly contributed to by the medical treatment of the deceased would be considered as a possible unnatural death.[58]

14.56 As indicated earlier, if a doctor is unable to certify the cause of a sudden death, the case must be formally reported to the coroner. The coroner is assisted in making decisions about whether an inquest should be held by his/her officer, who collects information he/she considers to be relevant for this purpose. In practical terms, although information may come to the coroner from a number of sources, the vast majority of information on which the coroner makes his decisions, at least in the case of a hospital death, comes from his/her officer.[59] Mr Haigh told the Inquiry that the officer will obtain most of his/her information from hospital staff and will frequently talk to the family of the deceased. However, at the Trust at least, there is no guidance given to the officer about who should be approached for information and it is not invariable that the family will be contacted at this stage. Mr Haigh's evidence suggested that this may have led to a gap in the information gathering process:

Q. Do you know how often he or she will get information from family members?

A. Frequently, but I couldn't put a percentage on it.

Q. Is it done as a matter of course?

A. No, not necessarily.

Q. Or only when the hospital's own paperwork indicates a possible issue?

A. No, it doesn't depend on the hospital paperwork. I think it depends on the circumstances and what investigations the coroner's officer thinks are appropriate.

Q. How would the coroner's officer know that a family might have things that they want to say about the care that was received by a patient?

A. I think the first port of call should be through the staff at the hospital, because as I've already said, if there are known to be real concerns about the treatment that someone has received, then it should be reported to me. But, of course, then, in those cases where the coroner's officer does speak to the family, then, of course, they can make their concerns known as well.

57 Coroners Act 1988, section 8; Coroners and Justice Act 2009, section 1 removes the "sudden" requirement in section 8(b)
58 Haigh T48.11–12
59 Haigh T48.14–15

Q. So does that rely on the hospital being frank with the coroner's officer, not just about potential contributions to death but also whether a family might have something to say about it?

A. Yes, I suppose it does, yes. Yes.

Q. Generally speaking, in this area, it sounds as though – and please tell me if this is wrong, it sounds as though you and your officer are very largely dependent on the information from the hospital itself to be accurate, in order to inform you.

A. Yes, I think that's correct.

Q. Does it go without saying that there's a risk that if doctors or administrators aren't candid, then cases that you should be dealing with could be missed?

A. That is certainly perfectly possible ...[60]

14.57 Mr Haigh went on to point out that when a MCCD is issued, a family member has to register it and, at that stage, certain questions are asked which may bring to light a reason for referral to him. There had been cases where matters had been referred to him by the registrar as a result of concerns expressed by the family, possibly once or twice a year in the case of the Trust.[61]

Disclosure of information to coroners

14.58 The case of John Moore-Robinson and the non-disclosure of the consultant's report to the coroner have been considered in *Chapter 2: The Trust* and *Chapter 22: Openness, transparency and candour*. There it was concluded that such information should have been disclosed to the Coroner and that appropriate guidance to Trust legal representatives and information managers is required.

14.59 Mr Haigh told the Inquiry that he considered he had a good working relationship with the Trust but he had experienced some difficulty in obtaining the attendance of doctors to give evidence at inquests.[62] He did receive a response from Dr Suarez offering to help and suggesting a procedure to ensure adequate notice was given.[63]

14.60 The good working relationship appears to have extended to reliance on the Trust to suggest which witnesses were necessary in a case. There does not appear to have been a process of analysing the medical records to establish who might be a relevant witness, or resort to expert advice to assist in establishing this. Indeed, Mr Haigh relied on the Trust to produce

60 Haigh T48.17–18
61 Haigh T48.18–19
62 Haigh WS0000005697, para 36
63 AH/4 WS0000005728

documentation it considered to be helpful, as indicated by the following passage from his evidence:

> *Q. In our period 2005 to 2009, from this trust, would you ask for standard sort of documents that they might hold or would you be looking at what you had already and focusing on specific requests?*
>
> *A. In terms of documents, I think the documents that immediately come to mind are medical records, and in most cases I will not examine the medical records, but I will request that they are available at the inquest to be looked at ... if necessary.*
>
> *Q. Did you expect the trust to provide you with any standard documents, such as serious untoward incident reports or adverse incident reports, or would you expect them only to provide such items if you specifically requested them?*
>
> *A. I believe my expectation was that if it was felt to be helpful to my inquest, then the hospital would send me the serious untoward incident report.*
>
> *Q. And who would decide that?*
>
> *A. I would imagine – I don't know but I would imagine the appropriate person in legal services at the hospital.*
>
> *Q. If you were not aware of the existence of such a report, then obviously you couldn't ask about it.*
>
> *A. True, but I would probably have an idea as to* [in] *what type of case there may have been a serious untoward incident report. So, technically, I could have asked if I'd wanted to.*
>
> *Q. But did you tend to do that, to ask in a case where you thought there might be or did you rely on the trust to give you what it saw as relevant?*
>
> *A. Probably the latter. I probably tended to rely on the trust providing me with the report I requested and any further information which they felt may be helpful.*[64]

14.61 He did concede that there were risks in this approach:

> *THE CHAIRMAN: I'm not for a moment suggesting that what you've just said isn't common in my professional experience in inquests throughout the country, but isn't that, as an approach, relying on the organisation which in some sense is being judged, subject, of course, to Rule 43, to decide what is helpful to you, when there's always the temptation for it to produce what is helpful to it?*

64 Haigh T48.53–54

A. Yes. I understand what you're saying there, but I think there are – there are two factors. First of all, that I am still asking for reports [from] *people I see as the appropriate clinicians. So the main people I should still get information from. And I think the second factor is, do remember the inquest is an inquiry, it's – its – its not a contest, and I would hope that interested persons at my inquest would assist and enable people at my inquiry rather than ... not provide information if it was going to be helpful.*

THE CHAIRMAN: Isn't it a relatively common experience that parties at inquests, rightly or wrongly, pursue their own interests?

A. Certainly that does happen. And I think particularly ... some lawyers who perhaps don't fully understand the inquest procedure, or perhaps they do, but there's an inclination on them to try and treat the inquest as a sort of try out for a civil negligence claim.[65]

Families' experience of the inquest process

14.62 The Inquiry heard evidence from bereaved families expressing dissatisfaction with various aspects of their experience. These included:

- The time taken before the inquest could be completed:
 - Mrs Janet Robinson had to wait 12 months before the inquest into the death of her son took place;[66]
 - Mrs June Locke complained that the inquest into the death of her daughter did not occur for 14 months after her death;[67]
- Lack of involvement:
 - Mrs Locke felt her family had been disadvantaged by not being sent any reports relied on before the inquest hearing;[68]
 - The same family found it difficult to understand the proceedings and felt the need for advice and support, which they were not offered;[69]
 - Mrs Christine Dalziel, on the other hand, described how she was allowed to challenge the accuracy of evidence being given by a consultant.[70] However, she was dissatisfied with the inquest process, which she felt failed to hold to account the hospital or all those she believed were responsible for neglectful treatment of her deceased husband;[71]
 - Patient Relative B, whose statement was read to the Inquiry, felt unable to ask questions about hospital care at the inquest into the death of her late husband because it was in public:

65 Haigh T48.54–55
66 Robinson WS0000000049, para 38
67 Locke WS0000001156, para 18
68 Locke T14.149–150
69 Locke T14.150–151
70 Dalziel WS0000000015, paras 26–28; T11.82
71 Dalziel T11.85

I half hoped that the coroner would have asked some questions about my husband's care in hospital. I did not have the courage at the time to ask any questions myself. I just wanted peace of mind without any publicity. My brother-in-law has suggested that inquests should be split into two parts, one part open to the public when factual information could be revealed and one part confidential for the consideration of personal issues, and I agree. I would have been prepared to have spoken in confidence to someone about the inquest but I was not offered the opportunity to make any statement in private. I feel that there are certain times when bereaved people in such stressful and harrowing circumstances do not want to open up in public.[72]

However, she had found the Coroner's staff helpful and efficient.

- Lack of understanding about why some witnesses were not called or the way in which evidence was adduced:
 - Mrs Robinson was aggrieved at the Coroner's refusal to call as a witness a friend of the deceased who had been present at his accident and in A&E, where he received what is now accepted to have been inadequate care;[73]
 - In the same case, the Coroner admitted the evidence of a junior doctor and did not require a consultant to give evidence;[74]
 - Mrs Locke was concerned that her family were not asked to prepare a witness statement.[75] She felt that her own oral evidence was cut short while the surgeon was allowed to give full answers.[76]
- Apparent insensitivity shown to families by Trust representatives and staff:
 - Mrs Robinson thought the Trust's solicitors' conduct was insensitive;[77]
 - Mrs Dalziel thought that the consultant's initial attitude towards her family was "bolshy". However, after she successfully challenged the accuracy of his evidence, he approached her after the hearing to apologise, and to suggest that she should take the case further;[78]
- The speed at which hearings were conducted:
 - Mrs Robinson thought that one and a half hours was insufficient.[79]

14.63 Not all witnesses were uncomplimentary about their inquests: Mr Ron Street, who attended the inquest before a jury into the death of Gillian Astbury, thought that those involved had

72 Patient Relative B T12.171–172
73 Robinson WS0000000050, para 41
74 Robinson WS0000000049, para 40
75 Locke T14.143–144
76 Locke T14.149
77 Robinson WS0000000050, para 43
78 Dalziel T11.86
79 Robinson WS0000000050, para 43

been adequately briefed and found satisfaction in the narrative verdict. It may not be without significance that the deceased's family had legal representation.[80]

14.64 Understandably, Mr Haigh considered that he could not comment on those individual cases which would have required him to justify judicial decisions, which is not within the remit of this Inquiry.[81] However, he made a number of general observations relevant to the concerns that had been raised:

- While coroners have a duty to conclude cases as soon as possible, it can on occasion take some time to do so;[82]
- It was his practice to listen to representations as to who should give evidence, but it is a matter for the coroner to decide what evidence should be admitted;[83]
- Hearings took as long as was necessary, so that some might be very short indeed and others very long;[84]
- People attending inquests are expected to behave in an appropriate manner;[85]
- On opening an inquest, he sends an information pack to relatives. In this is a request for relatives to provide him with any information they consider relevant, and a standard Ministry of Justice leaflet explaining the role of coroners and inquests;[86]
- He may arrange for his officer to take witness statements. However, he could not think of a hospital case in which he had asked his officer to take a statement from a witness.[87]

Rule 43 reports

14.65 Under Rule 43 of the Coroners Rules 1984:

> *A coroner who believes that action should be taken to prevent the recurrence of fatalities similar to that in respect of which the inquest is being held may announce at the inquest that he is reporting the matter in writing to the person or authority who may have power to take such action and he may report the matter accordingly.*[88]

14.66 A 2008 amendment changed the rule to provide for a more elaborate procedure:

> ***43***.–*(1) Where–*
>
> *(a) a coroner is holding an inquest into a person's death; and*

80 Street T12.91–92
81 Haigh WS0000005703 para 62
82 Haigh WS0000005703 para 65
83 Haigh WS0000005704 para 66
84 Haigh WS0000005704 para 67
85 Haigh WS0000005704 para 68
86 Haigh WS0000005690 para 10
87 Haigh WS0000005707 para 79
88 Coroners Rules 1984 [SI/1984/552], rule 43

(b) the evidence gives rise to a concern that circumstances creating a risk of other deaths will occur, or will continue to exist, in the future; and

(c) in the coroner's opinion, action should be taken to prevent the occurrence or continuation of such circumstances, or to eliminate or reduce the risk of death created by such circumstances,

the coroner may report the circumstances to a person who the coroner believes may have power to take such action.

(2) A report under paragraph (1) may not be made until all the evidence has been heard except where a coroner, having adjourned an inquest under section 16 or 17A of the 1988 Act, does not resume it.

(3) A coroner who intends to make a report under paragraph (1) must announce this intention before the end of the inquest, but failure to do so will not prevent a report being made.[89]

14.67 A copy of the report must be sent to the Lord Chancellor and may be sent to any other person the coroner believes may find it of use or interest. The Lord Chancellor publishes an annual report summarising all Rule 43 reports received.

14.68 The person to whom the report is addressed is required to respond to the coroner within 56 days, but there is no legal requirement that any action is taken on the report, and no sanction is prescribed for a failure to reply, although it may be recorded by the Lord Chancellor in any report he/she publishes.[90]

14.69 As pointed out in Ministry of Justice Guidance, the new power was broader than the earlier one, which was limited to making reports with a view to preventing fatalities similar to that which was the subject of the disquiet. The new power extended to reports where action could be taken to prevent any fatality.[91]

14.70 Mr Haigh considered that the purpose of a Rule 43 report was:

to draw to the attention of a third party the concern raised during the inquest with a view to that person analysing it and seeing whether something ought to be done.[92]

89 Coroners (Amendment) Rules 2008 [SI/2008/1652] Reg 2, in force as of 17 July 2008
90 Coroners Rules 1984, as amended, rule 43A; *Guidance for Coroners on Changes to Rule 43: Coroner reports to prevent future deaths* (2008), Ministry of Justice, para 4.8
91 Coroner Rules 1984, as amended, rule 43; *Guidance for Coroners on Changes to Rule 43: Coroner reports to prevent future deaths* (2008), Ministry of Justice, para 2.2
92 Haigh WS0000005693, para 20

14.71 The 2008 amendments led Mr Haigh to change the style of his reports:

> *Prior to the rule change in July 2008 my Rule 43 reports were informal in style insofar as they did not specifically state within them that they were Rule 43 reports. I felt that I did not need to be overly formal when issuing the reports as the organisations to which I sent them took them seriously and responded. However, as a result of the change in the rules, the Rule 43 reports which I now issue are more formal insofar as they now clearly state they are being made under Rule 43. Owing to the rule change the reports are also circulated to a wider body of people and require a response within 56 days.*[93]

14.72 Before 2008, Mr Haigh kept no record of the number of reports he sent out as he was not required to do so, and while he had expected a reply to all such reports, there was no active monitoring of responses.[94] As he explained:

> *Well, I think, really, you should look at it within the context of my workload. I'm dealing with an individual case. I hold my inquest, then following the inquest I send my Rule 43 report. And then to a great extent, and this may seem blunt, then that's it. I'm now moving on to the next matter to be dealt with. I expected to get a response but, no, I didn't have a system for saying "Ah, yes, I need to do a diary note or some sort of system for chasing up on that Rule 43 report that I'd sent.*[95]

14.73 He believed that he had received a response in most cases, but on reviewing some of the reports he had retained he concluded that in some cases he had not.[96] He considered it had been a weakness in the system that he had no power to require information to be given.

14.74 He agreed that the absence of a formal record of reports and responses might have hindered his ability to detect themes at the Trust, but he pointed out that he was not required to undertake such a role by the legislation.[97]

14.75 Since the new rule was introduced Mr Haigh has changed his practice. He now keeps a record of all reports and chases up responses if one is not received within the time limit set. Where he did ask to receive a response which indicated that his concerns were being addressed, he would not hesitate to write again to impose further pressure, although he could not recollect ever having done this.[98] It seems that reports are not regularly shared with regulators such as the Care Quality Commission (CQC) and he agreed that this could be done without undue administrative burden.

93 Haigh WS0000005692, para 19
94 Haigh WS0000005693, para 22
95 Haigh T48.87
96 Haigh WS0000005693, para 22
97 Haigh T48.89–90
98 Haigh WS0000005694, para 26

14.76 With regard to reports about the Trust, Mr Haigh was able to produce 17 reports or letters issued between 2005 and 2009 and it is possible that there were others.[99] To find all reports he would have had to undertake a physical search of all his files, which was not practicable. It appears that records of cases are not kept in a way which enables him to identify those which relate to the Trust.[100] He did not believe he made significantly more reports about the Trust than about Queen's Hospital, Burton.[101]

14.77 Four of the 17 Rule 43 reports/letters did not receive responses: a 21 March 2006 letter questioning, in general terms, the circumstances of a death; a report sent on 11 June 2006 concerning a breakdown in communication between an ambulance crew and medical staff; a letter sent on 10 April 2007 regarding a patient who had been suddenly discharged and left in the cold; and a letter sent on 17 June 2008 concerned with the comparison of medical and nursing records.

14.78 Further, a Rule 43 report sent on 16 October 2007 concerning the storage of medical records and additional checks on patients received an initial response letter but no further communication.[102]

14.79 The remaining 12 reports/letters received adequate responses. However, one was received only after a considerable (two-and-a-half-month) delay.[103] These responses pointed to the Trust's existing policy and outlined steps it would take to rectify the area of concern.

14.80 The reasons for these Rule 43 reports/letters included:

- Discharging a patient to a nursing home without any indication that the patient had contracted *C. difficile*;
- Poor hygiene, low staff morale and staff shortages;
- The A&E protocol dealing with the risk of spleen ruptures;
- Patients falling over and injuring themselves on wards, and bed buzzers not working properly;
- Patients being left in soiled nightwear;
- A patient being prescribed a drug to which she was allergic;
- The monitoring of patients with alcohol addiction problems.[104]

14.81 After the change in the rules, more formal Rule 43 letters were sent to the Trust. Mr Haigh gave two examples. One sent on 6 October 2008 raised a concern about X-rays and received a response on 14 November. The other was sent on 11 February 2009 and concerned the

99 Haigh WS0000005698–702, paras 38–61
100 Haigh WS0000005698, para 38
101 Haigh WS0000005695–696, para 30
102 Haigh WS0000005700, para 51
103 Haigh WS0000005700, para 48
104 Haigh WS0000005698–702, para 40–59

effectiveness of communications between nurses and doctors and junior doctors' workload. The latter received a very detailed response from Dr Deborah Fox, which Mr Haigh felt was due to the Trust being under investigation and therefore "keen to ensure that its house was in order."[105]

14.82 Mr Haigh thought that on about six occasions a year the Trust sent him information about an action plan or similar material relevant to a case which he could then put to a witness to explore issues.[106] Receipt of such information would have reduced the possibility of his sending a Rule 43 report.

14.83 Andre Rebello, HM Coroner for the City of Liverpool and Secretary of the Coroners' Society of England and Wales, expressed doubts over whether the coronial system could be effective in providing early warnings of worrying patterns of care:

> *I have been asked if there is any potential for the Coroner's Office to be used to provide an early warning system to identify a failing hospital. My response is that there are many other bodies which have a legal duty to do this and be vigilant in terms of monitoring standards of healthcare. The unfortunate reality is that coroners are only provided with the resources to carry out their statutory duties, so if we start trying to be a watch dog for healthcare and other regulatory bodies, we simply would not be able to do our job properly. Further, if the Government imposed additional regulatory responsibilities on coroners this would have to be funded with new money.*[107]

Conclusions

Certification of death

14.84 The Third Report of the Shipman Inquiry, already referred to, identified a number of weaknesses in the certification system which have also been suggested by the evidence to this Inquiry.

14.85 The attitude attributed by Kath Fox (UNISON representative at the Trust) to the coroner's office of reluctance to compromise family sensitivities about post-mortems is an echo of the evidence received by Dame Janet Smith from a coroner who found in a survey a significant willingness among doctors to "modify" a certificate to avoid a post-mortem or to avoid distress to families.[108]

105 Haigh WS0000005702, para 60–61
106 Haigh WS0000005697, para 37
107 Rebello WS0003000074, para 48
108 *Third Report – Death certification and the investigation of deaths by coroners* (14 July 2003), Chapter 5, para 5.39, www.shipman-inquiry.org.uk/thirdreport.asp

14.86 Dame Janet also observed the phenomenon seen here of hospital staff claiming that pressure is exerted by coroner's officers, and coroners denying that this occurs:

> *Some doctors complain that, if they telephone to say that they are not sufficiently sure of the cause of death, the coroner (or more likely the coroner's officer) will indicate that s/he is not willing to accept the case (an oft-used phrase seems to be that "the coroner won't be interested") and will seek to persuade the doctor to issue an MCCD. The doctor feels under pressure to do so because, if the coroner will not accept the case and the doctor refuses to issue an MCCD, the relatives are unable to register the death or dispose of the body ... Coroners deny that this kind of situation ever arises. They say that they are always willing, even anxious, to take on cases that require investigation. It may be that sometimes the problem is one of misunderstanding or of differing perceptions of the respective roles of the coroner's office and the certifying doctor. The coroner or coroner's officer might genuinely believe that the doctor is being over-cautious about certifying the cause of death.*[109]

14.87 As Dame Janet observed:

> *The present system depends almost entirely on the good faith and judgement of the doctor who signs the MCCD or decides that the case should be reported to the coroner. It also depends on the courage and independence of doctors, for the system places upon them some responsibility to police their colleagues, for example by refusing to certify a death which may have been contributed to by some misconduct, lack of care or medical error on the part of a professional colleague. It may not be easy for a junior member of the clinical team responsible for the care of the deceased to withstand the expectation that s/he will certify the cause of death, rather than report the case to the coroner for investigation.*[110]

14.88 The evidence before this Inquiry suggests that the issue of pressure on doctors to certify a cause of death was still prevalent in Stafford during the period under review. This was not because of any intention on the part of the Coroner or his office to dissuade doctors from doing their duty correctly but, as can be seen from Mr Haigh's explanation of the challenge that might typically take place, an expectation that in most cases it should be possible for a cause of death to be identified. However, what was expressed with that intent may well have been understood, particularly by an inexperienced junior doctor, to be suggesting less appropriate behaviour. That would explain how different perceptions could be harboured in the hospital and in the coroner's office as found by Dame Janet in the Shipman Inquiry.

109 *Third Report – Death certification and the investigation of deaths by coroners* (14 July 2003), Chapter 5, paras 5.55–5.56, www.shipman-inquiry.org.uk/thirdreport.asp

110 *Third Report – Death certification and the investigation of deaths by coroners* (14 July 2003), Chapter 5, para 5.26, www.shipman-inquiry.org.uk/thirdreport.asp

14.89 At the root of this problem is likely to have been the tendency of consultants, to whom the responsibility should have fallen, to leave the certification of the cause of death to junior doctors still in training, without adequate support.

14.90 Problems of this nature are likely to be much reduced by the introduction under the Coroners and Justice Act 2009 of IMEs, whose role will include scrutiny of medical certification in hospital deaths, as described earlier. It is a matter of some regret that the development of this project has been subject to some delay, apparently caused in part by funding issues arising out of the transfer to local authorities of responsibility for providing IMEs. It appears that the pilot projects have been well received, and that a well run and resourced system of IMEs should reduce the chances of misreporting and mis-recording of the cause of death. This should in turn increase the prospects of poor care being detected and investigated. At the same time, coroners will be given a source of expert support that is currently lacking.

14.91 While the concept of the IME scheme is a very positive step, the evidence suggests that attention needs to be paid to certain matters of detail to ensure it is as effective as possible:

- It is of considerable importance that IMEs are independent of the organisation whose patients' deaths are being scrutinised. This will not always be easy to arrange, but public confidence in the scrutiny involved will be diminished if judgements about possible concerns around the standard of treatment are in the hands of an employee of the trust and colleague of the doctors concerned;

- Sufficient numbers of IMEs need to be appointed and resourced to ensure that they can give proper attention to the workload. Dr Alan Fletcher's pilot scheme did not include scrutiny of deaths in the community and even so his workload appeared to be potentially oppressive for something which is intended to be a part-time activity. An average time of 20 minutes spent considering a case may be adequate in most instances, but some complicated histories will require significantly more time. Neither the public interest nor the needs of bereaved families will be well served by rushed consideration, probably resulting in some unnecessary referrals to the coroner;

- National guidance in whatever form it takes must set out standard methodologies for approaching the certification of the cause of death to ensure so far as possible that similar approaches are universal;

- It should be a routine part of an IME's role to seek out and consider any SUI or adverse incident reports relating to the deceased, to ensure that all circumstances are taken into account whether or not referred to in the medical records;

- The "Shipman question" should be asked of the certifying doctor in addition to the bereaved family, (ie whether there are any concerns or anything unusual about the circumstances surrounding the death they wish to draw to the attention of the coroner), and guidance should be given to hospital staff encouraging them to raise any concerns they may have with the IME;

- Dr Fletcher described a model approach to bereaved families aimed at finding out if they had concerns.[111] It is important that IMEs and any others having to approach families for this purpose have careful training in how to undertake this sensitive task in a manner least likely to cause additional and unnecessary distress;

- So far as is practicable, the responsibility for certifying the cause of death should be undertaken and fulfilled by the consultant, or other senior and fully qualified clinician, in charge of a patient's case or treatment. The evidence before this Inquiry and the Shipman Inquiry suggests that junior doctors have had an unfair burden placed on them in this regard which has rendered the process of certification much less of a safeguard than it should be.

Appointment of assistant deputy coroners

14.92 There is no evidence of any impropriety arising out of the appointment of Mr Knowles as an assistant deputy coroner in spite of his position as Trust Solicitor during the material time. He did not sit on inquests involving the Trust and there can be no suggestion that the relationship between Mr Knowles and Mr Haigh prejudiced any inquests involving hospital deaths. In spite of the pains Mr Haigh and Mr Knowles obviously took to avoid anything inappropriate in this regard, it is less clear that a perception of bias could not conceivably arise. There appears to have been nothing to rule out Mr Knowles handling correspondence or calls for advice in relation to Trust-related cases. Again, there is no evidence that this actually happened. For the avoidance of doubt, the position was not affected by the criticism made of Mr Knowles regarding the Moore-Robinson case.

14.93 In any locality, there is always the risk that persons sitting in a judicial capacity will be asked to deal with cases which it would be inappropriate for them to undertake because of a connection with persons or organisations involved in the case. Generally, such issues are easy to address because they are isolated occurrences and alternative arrangements can be made easily and transparently. The chance of a perception of an inappropriate connection with a person or organisation involved in a case is higher where the organisation concerned is a local hospital. Many deaths in any area will occur in the local hospital or involve a history of treatment given there. A solicitor for a hospital trust is likely to have multiple and frequent contacts with the local coroner. It will therefore be correspondingly more difficult for such a

111 Fletcher T37.101–103

coroner to avoid the suggestion that association with such a solicitor as his/her deputy might lead to a perception of inappropriate contact.

14.94 The new system for appointments, which is likely to follow implementation of the Coroners and Justice Act 2009, provides an opportunity to avoid this sort of problem. Where it is proposed that a person be appointed as an assistant deputy coroner, the appointment will require the Lord Chancellor's consent. It would be possible for the Lord Chancellor to issue guidance as to the criteria which ought to be adopted in such appointments. The Chief Coroner too could issue guidance on how to avoid the appearance of bias where assistant deputy coroners are associated with a party involved in a case. The key to maintaining confidence in the system is a transparent arrangement for preventing any conflicts, or perceived conflicts of interest arising.

Decisions on the holding of post-mortems/inquests

14.95 As Mr Haigh pointed out, hospital-related deaths are but a small part of the range of cases he has to deal with, and the focus of this Inquiry has necessarily been on that part of his work. It is not intended to be a criticism of Mr Haigh to observe that the system for gathering information to allow a decision to be made on whether to hold an inquest in hospital cases has been unsatisfactory. The problems that have been exposed by the evidence include:

- An absence of guidance to coroners' officers about whom to approach for information;
- An inconsistent practice with regard to approaches to families. It should be a minimum requirement of a coroner's practice that the bereaved family are, where practicable, approached to give them an opportunity to raise concerns, and to answer any suggested by other sources. While the coronial process is to protect the public interest in a number of respects, it will be, in most cases, the bereaved family who are most closely affected by the decisions taken by a coroner, and they will also often be a source of highly relevant information. The intended future practice described by Dr Fletcher will address this concern to a great extent, but there will remain a need to involve the family in the coroner's process, providing them with clear and sensitive advice about it, and receiving their observations on what is proposed. It is therefore inevitable that early contact will need to be made with the family by the relevant coroner's office in any case where a post-mortem or inquest is under consideration;
- An absence of a system allowing coroners to maintain accessible and analysable data about their cases. Mr Haigh has, through his own initiative, taken action to address this, but a consistent approach nationally could be better achieved by guidance and appropriate resourcing of coroners to enable them to keep an orderly record system.

Disclosure of information to coroners

14.96 It is clear from the sorry story of the case of John Moore-Robinson (see *Chapter 2: The Trust*) that there is a need for firm guidance to be provided to healthcare organisations about the importance of frank disclosure to coroners. It must be appreciated that it is for coroners to decide what information is relevant, but they cannot undertake their obligation to inquire into a death if they have to rely on an interested party's view of what might be "helpful", given the difficulties for even the most conscientious representative of making an objective judgement about material which may lead to criticism of his/her organisation. Coroners cannot rely on bereaved family representatives detecting omissions in the evidence: they may not have the experience or the will to make such points, particularly if, as will often be the case, they are not represented by experienced medical lawyers or any lawyers at all.

14.97 If an inquiry is to be properly conducted into the cause of a death in hospital where the standard of care may be implicated, it is difficult to see how coroners can avoid undertaking an analysis of the records, if necessary with expert help, to identify the issues and the potential witnesses. To rely on the hospital's selection of evidence requires a degree of trust that sadly cannot always be justified. Even if it can be – and cooperation is always desirable – the process will not attract the confidence of families and the public if it is not a proactive inquiry rather than a passive one.

14.98 Mr Haigh's approach cannot be criticised for being inconsistent with common practice: the contrary has not been suggested. It is also right to point out that coroners often have very limited resources, which makes proactive inquiry difficult. However, the arrival of IMEs may make their task easier in this regard. IMEs should be available to undertake the relevant analysis or to advise coroners as to how it can be done and to what extent it is necessary.

14.99 On a similar note, guidance to coroners should encourage them to insist on having the senior doctor responsible for the delivery of care to a patient give evidence, even if he/she was not present at the time of death. It is often wholly inappropriate, as in the case of John Moore-Robinson, for evidence to be taken only from an inexperienced junior doctor, who, inadvertently, may mislead the coroner on both clinical matters and the expectations of practice.

Rule 43 reports

14.100 A coroner's only relevant duty is to inquire into the cause of death in individual cases and to conduct inquests in defined circumstances. He/she is emphatically not a regulator, and many of his/her cases have nothing to do with healthcare in any event. Coroners have neither access to the relevant information, power to obtain it, nor resources available to analyse it in order to enable them to monitor trends and developments at a hospital. In relation to departures from standards of care, their remit is limited to cases of serious or systemic neglect

which may have caused or contributed to death. However, the evidence they obtain in the course of their duties has considerable potential value to healthcare commissioners and regulators in assisting them in their duties.

14.101 Before the 2008 amendments, coroners had no incentive to maintain any systematic record of hospital deaths and Mr Haigh cannot be criticised for not doing so. Further, he cannot be criticised for not following up responses received from the Trust assuring him that action had been taken. He had no power to take further steps.

14.102 The 2008 amendment has brought some improvements. The obligation on the Lord Chancellor to publish a report means that missed Rule 43 reports about a hospital end up in the public domain at least in summary form. Due to the obligation to make a return to the Lord Chancellor, coroners have to keep records of their reports in a more systematic way.

14.103 The main improvement, which could be made to current practice, is that coroners should be required to send a copy of any healthcare related report to the relevant commissioner and to the CQC. As most such cases should probably have been registered as SUIs in any event, this may result in commissioners and the CQC receiving reports of matters of which they are already aware but the public interest will be better protected if the coroner takes this step, as he/she is entitled to do under the Coroners Rules. This approach would also ensure that the information was available earlier than would be the case if the Lord Chancellor's report is relied upon for this purpose.

Summary of recommendations

Recommendation 273

The terms of authorisation, licensing and registration and any relevant guidance should oblige healthcare providers to provide all relevant information to enable the coroner to perform his function, unless a director is personally satisfied that withholding the information is justified in the public interest.

Recommendation 275

It is of considerable importance that independent medical examiners are independent of the organisation whose patients' deaths are being scrutinised.

Recommendation 276

Sufficient numbers of independent medical examiners need to be appointed and resourced to ensure that they can give proper attention to the workload.

Recommendation 277

National guidance should set out standard methodologies for approaching the certification of the cause of death to ensure, so far as possible, that similar approaches are universal.

Recommendation 278

It should be a routine part of an independent medical examiners's role to seek out and consider any serious untoward incidents or adverse incident reports relating to the deceased, to ensure that all circumstances are taken into account whether or not referred to in the medical records.

Recommendation 279

So far as is practicable, the responsibility for certifying the cause of death should be undertaken and fulfilled by the consultant, or another senior and fully qualified clinician in charge of a patient's case or treatment.

Recommendation 280

Both the bereaved family and the certifying doctor should be asked whether they have any concerns about the death or the circumstances surrounding it, and guidance should be given to hospital staff encouraging them to raise any concerns they may have with the independent medical examiner.

Recommendation 281

It is important that independent medical examiners and any others having to approach families for this purpose have careful training in how to undertake this sensitive task in a manner least likely to cause additional and unnecessary distress.

Recommendation 282

Coroners should send copies of relevant Rule 43 reports to the Care Quality Commission.

Recommendation 283

Guidance should be developed for coroners' offices about whom to approach in gathering information about whether to hold an inquest into the death of a patient. This should include contact with the patient's family.

Recommendation 284

The Lord Chancellor should issue guidance as to the criteria to be adopted in the appointment of assistant deputy coroners.

Recommendation 285

The Chief Coroner should issue guidance on how to avoid the appearance of bias when assistant deputy coroners are associated with a party in a case.

Chapter 15
Risk management: the National Health Service Litigation Authority and the National Clinical Assessment Service

Key themes

- The NHS Litigation Authority (NHSLA) process for assessing trusts against its standards was potentially valuable for looking at risk management processes but was wrongly thought by some to verify the presence of good quality care.
- Although its system was complied with in the assessment of the Trust in 2007 no cause for concern was found. This suggests that it was not capable of detecting the very high risk that the Trust then posed, and raises questions about the purpose of the NHSLA rating system.
- The Trust used its NHSLA rating in support of its self declarations to the Healthcare Commission (HCC) and in its foundation trust (FT) application.

Introduction

15.1 The NHS has had the benefit of the support of a risk management service in the form of the NHS Litigation Authority (NHSLA) since 1995. It has also had the availability of assistance with cases involving "problem" doctors since 2001 from the National Clinical Assessment Service (NCAS). As NCAS is also designed to reduce risk – both for the employer and the employee – and as there is a plan to merge it with the NHSLA from 1 April 2013, it is appropriate to consider their involvement in one chapter.

NHS Litigation Authority functions

15.2 The NHSLA was established in 1995 as a Special Health Authority accountable through its Chair to the Secretary of State for Health, who determines its broad policy objectives and financial framework. Those policy objectives are implemented by the organisation's Board. Its principal function is to manage the Clinical Negligence Scheme for Trusts (CNST), which is a

risk-pooling scheme that indemnifies NHS organisations against clinical negligence claims made against them. The CNST is associated with a programme of assessment of those organisations against risk management standards, which is designed to reduce the volume of claims.

15.3 Mr Steven Walker, Chief Executive of the NHSLA from its inception until 2012, made it clear that the organisation is not a regulator:

> *The objective of the* [CNST] *was to encourage trusts down the pathway of adopting good practice and policy.*[1]

15.4 The NHSLA is not technically an insurer, but it effectively operates as one for members of the CNST. Organisations which join the CNST pay the NHSLA an annual premium, the amount of which is determined by claims data and other information considered by a firm of actuaries.[2] The relationship between this premium and the risk management standards is considered below.

15.5 As its name suggests, the NHSLA conducts litigation on behalf its member trusts and foundation trusts (FTs) in civil clinical negligence claims brought against them for damages. That function is not considered in detail here, but it is a function which gives rise to some of the areas which are relevant to NHS culture and organisational behaviour.

Encouraging openness

15.6 The NHSLA has periodically issued guidance to its members encouraging the use by them of apologies and explanations when a complaint or claim is made, where this is justified.

15.7 Mr Walker, told the Inquiry that it is committed to:

> *... a less adversarial and more cost-effective way of resolving disputes about health care and medical treatments.*[3]

15.8 This commitment extends beyond the requirements of the relevant civil procedure protocol and rules. For example, the NHSLA had a policy of obtaining early expert advice where it is likely that liability will be denied, in order to be able to respond as fully as possible to the allegations made. Mr Walker said:

1 S Walker WS(3) – WS0000053683, para 13
2 S Walker WS(2) – NHSLA0001000329, para 32
3 S Walker WS(2) – NHSLA0001000324, para 6

We are therefore engaged in open discussions at an early stage and try to take an informed view based upon an early and detailed consideration of the issues.[4]

15.9 A series of circulars has been issued to members, agreed with and co-signed by organisations such as medical defence organisations, the British Medical Association (BMA) and the General Medical Council (GMC), encouraging early and full apologies and explanations. A circular from May 2009 states the following:

> ***Apologies***
>
> *It is both natural and desirable for clinicians who have provided treatment which produces an adverse result, for whatever reason, to sympathise with the patient or the patient's relatives; to express sorrow or regret at the outcome; and to apologise for the shortcomings in treatment. It is most important to patients that they or their relatives receive a meaningful apology. We encourage this, and stress that apologies do not constitute an admission of liability. In addition, it is not our policy to dispute any payment, under any scheme, solely on the grounds of such an apology.*
>
> ***Explanations***
>
> *... In this area, too, the NHSLA is keen to encourage both clinicians and NHS bodies to supply appropriate information whether informally, formally or through mediation.*
>
> *Explanations should not contain admissions of liability. For the avoidance of doubt, the NHSLA will not take a point against any NHS body or any clinician seeking NHS indemnity, on the basis of a factual explanation offered in good faith before litigation is in train.*[5]

15.10 Further, the NHSLA requires its members, through its risk management standards:

> *... to have "an approved documented process for ensuring that all communication is open, honest and occurs as soon as possible following an incident, complaint or claim that is implemented and monitored".*[6]

15.11 Stuart Knowles, the Trust's former solicitor, whose conduct of one claim on behalf of the Trust is considered elsewhere, thought that there were great difficulties in meeting both the normal requirements of litigation on behalf of a trust and the requirement to be open:

4 S Walker WS(2) – NHSLA0001000325, para 12
5 NHSLA0001000001, Letter to Chief Executives and Finance Directors of all NHS Bodies (May 2009), NHSLA, p1
6 S Walker WS(2) – NHSLA0001000327, para 23

... the NHSLA in their advice I think presuppose that the litigation train hasn't been put in place, because I think once that has been put in place, for whatever reason, and certainly until two or three years ago, almost – or every NHS organisation would be encouraged to actually stop discussion or dealing with complaints, as far as patients is concerned.

Now, that has changed by the rules, and so there is, if you like, more openness there. This is, I think, an extremely difficult position for the NHS, because on the one hand the NHSLA are tasked with the management, ... of handling clinical negligence claims and all that entails from that, but on the other hand to endorse and encourage the movement and change within the NHS and within clinicians generally to be more open in their approach to patients ...

I think it is right, from a personal perspective, that discussion is open. That must be right. But it's a difficult tightrope. I'm not quite sure that it's a conflict ... I think it's a tightrope. It's a difficult balance for NHS clinicians and managers to achieve ... How can you enter into a meaningful dialogue with individual patients or their families without, if you like, making admissions which are effectively a breach of duty of care and potentially a breach of causation negligence, if you like, at the same time? It is a fine tightrope.

I think the advice is ... fair. I think it's exceptionally difficult when you're on the ground to put in practice. But to be honest, I am not sure that it could be phrased in any other way.[7]

15.12 As Mr Knowles also said, there has been a change of approach over a number of years in the field of clinical negligence litigation and in the NHS. The position has moved from a closed approach with little voluntary sharing of information, to one of more openness, and a willingness to settle justifiable claims at the earliest opportunity. With all due respect to his experience as a solicitor, however, it should not be difficult to distinguish, where appropriate, between an open explanation and an admission of liability for a claim. A full explanation is likely to be appropriate even where an admission of liability is not. Indeed, the pre-action protocol for clinical negligence claims effectively requires this in response to a claim if only to set out the reasons why it is not being accepted. An explanation may also be interim, based on the organisation's understanding of events pending further enquiries.

15.13 An apology should not be confused with an expression of sympathy: one or other or both may be appropriate, depending on the circumstances. An expression of sympathy will almost always be appropriate whatever the position with regard to blame or fault, if a complainant or claimant has sustained some injury or illness or other misfortune. An apology may be appropriate where it has been established that a substandard service has been given in some respect, even if this has not or may not have caused the harm or distress under complaint.

7 Knowles T131.27–28

15.14 It is, however, clear that both full, frank and accurate explanations, and well-expressed and authoritative apologies, are particularly appropriate where harm has or may have been caused by an action or omission on the part of a healthcare provider, whether or not any individual, or the organisation itself, is liable in negligence. There are two main benefits:

- The complainant or claimant may be satisfied with such steps as resolving the grievance. It may assure them that what happened to them will not happen to others. It should, if communicated effectively and sensitively, help reduce feelings of distress;
- For the NHS the likelihood of an unnecessary claim being pursued may be reduced.

15.15 For these reasons, the NHSLA is absolutely right to encourage openness as demonstrated through explanations and apologies. What it should seek to encourage its members to avoid are inaccurate, less than frank explanations and formulaic apologies, which are likely to increase the sense of grievance and feelings of distress, as well as increase the chances of litigation.

Relevance of claims information

15.16 The NHSLA, inevitably in the course of its litigation function, collects information about the nature and number of claims brought against all member trusts. Members are sent a quarterly report on the claims made against them.[8] However, this information is of little help in enabling members and others to assess their current performance for two reasons:

- Claims represent only a small proportion of all adverse incidents;
- Many claims are brought a long time after the event and therefore do not necessarily reflect the current state of affairs.[9]

15.17 Each year, the NHSLA writes to each trust with a risk management report on its new, outstanding and unresolved claims seeking information on what action has been taken to reduce risk. The Inquiry was shown examples of these reports, which include in summary form: the facts of the case, the risk issues raised, including clinical performance failures, and the action, if any, taken to date to remedy the concerns.[10]

15.18 It appears that this is imposing a significant burden on the NHSLA's resources and the Inquiry was told that the frequency of reports may have to be reduced.[11]

8 S Walker WS(1) LA0000000009, para 6.2
9 S Walker WS(3) WS0000053681, para 8
10 AB/33 WS0000055821; AB/34 WS0000055823
11 S Walker WS(3) WS0000053688, para 38; Bartholomew WS0000054723, para 119

NHS Litigation Authority risk management standards

Purpose of risk management

15.19 There are three parts to the NHSLA's risk management function:

- Setting risk management standards for all NHS organisations in England;
- Assessing the organisations against those standards;
- Educating the organisations about risk management.[12]

15.20 The NHSLA told the Inquiry that risk management was:

> *... a mechanism for putting in place processes for the management of risks which are identified in a particular context.*[13]

15.21 It was not, they said, an audit mechanism, nor an inspection. It was a process that was the responsibility of each organisation to undertake.

15.22 The assessment of a trust's risk management undertaken by or on behalf of the NHSLA was not a direct measurement of how many or what risks have occurred.

15.23 The existence of a risk management system, even one complying with the NHSLA standards, does not of itself mean that a hospital managed by a trust is safe. In September 2005, a newspaper local to Stafford published an article reporting the Trust's attainment of CNST level 3 with the headline: "Trust judged among safest in country."

15.24 It purported to quote a Trust spokesman:

> *Mid Staffordshire General Hospitals NHS Trust is one of the eight safest Trusts in the country after gaining the highest level of accreditation under a scheme measuring the management of clinical risk ... The deputy director of clinical standards Trudi Williams said: "This demonstrates that as a Trust that we've put everything in place to reduce risks as far as possible. That means providing the safest possible service to patients".*[14]

15.25 Ms Williams denied making the statements attributed to her, and that is accepted. It would be wrong to criticise the Trust for an article such as this when the Inquiry has received no direct evidence of how this article came to be written. However, the article overstated the significance of the NHSLA risk management standards. They do not in themselves ensure

12 CLO0000002713–714, *Counsel to the Inquiry closing submission*, Chapter 20 – The NHS Litigation Authority
13 CLO0000001156, *Closing submissions of the NHSLA*, para 19
14 TAW/3 WS0000019224

that a trust is safe, although they are regarded, according to the NHSLA itself, as being an important driver for patient safety.[15]

15.26 Alison Bartholomew, Risk Management Director of the NHSLA, told the Inquiry:

> *One of the functions of the NHSLA is to promote improvement in patient and staff safety by encouraging better risk management practices within NHS organisations in England.*[16]

15.27 The NHSLA does not consider that its standards and assessments are necessarily part of the information on which the public is expected to rely. Mr Walker told the Inquiry:

> *Q: … are the CNST standards really something to which patients are able to relate?*
>
> *A: In practice, patients very rarely do. We rarely have any enquiries or questions, either from patients or their representatives, about CNST. The – the risk management element of CNST is primarily directed towards our members. It's member-facing. We're very frank about outcomes. As you probably know, we're Freedom of Information Act obsessive, we publish everything, but I'm not here making a case that members of the public regularly visit our website before choosing which hospital they're going to go to. They may have visited the HCC, they might visit CQC, I just don't know. But we've never imagined that they visited ours on a regular basis and we've never seen any evidence to suggest they do.*
>
> *Q: I think I should have put my question a bit better. What assurance can a patient draw from standards which indicate that certain processes are in place without a focus on outcomes or without consideration to outcomes?*
>
> *A: Only that those processes are in place. That was my point.*[17]

15.28 He rejected in strong terms the proposition that the standards assessments could be relied on for an indication that a trust had satisfactory standards of care or safety:

> *… anyone who says that they took comfort from what the NHSLA or Monitor concluded about standards at the Trust is deluding themselves.*[18]

15 CLO000001159–60, *Closing submissions of the NHSLA*, para 35
16 Bartholomew WS0000054686, para 4
17 S Walker T111.152
18 S Walker WS(3) – WS0000053690, paras 46–47

... I imagine it's entirely possible that people could read more into our level 2 or level 3 than they would were they able to access all of the documents and determine exactly what it is that we're assessing against. We've never said that this was a Good Housekeeping seal of approval. This is all about incentivising trusts, expressly as stated in our statutory instruments, to improve their risk management standards.[19]

15.29 There has been a variable practice with regard to the inclusion of a disclaimer in assessment reports. The 2010 and 2011 reports on the Trust stated on the front page:

The comments and findings of the assessment recorded in this report reflect the opinions of the assessors based on the evidence provided by the organisation in relation to the requirements contained in the relevant standards manual. They should not be read as approval in any other context.[20]

15.30 The 2007 report had no such disclaimer.[21]

Types of risk management standards

15.31 The NHSLA maintains two sets of standards, a general standard applicable to all acute trusts, and a specific standard for maternity services. The latter was introduced because of the greater risk of high value negligence claims in that specialty. The detail of the specialist standard was not considered by the Inquiry, but it should be noted that the NHSLA considers it would be an enormous task to create specialist standards for every specialist area. However, the NHSLA has been considering extending this approach to surgery and A&E.[22] These would bring together standards and guidance issued by national organisations such as the College of Emergency Medicine, including guidance on staffing levels. It is possible they would add a new Level 4 classification to the assessment of compliance.

The 2004 generic standards

15.32 The 2004 standards contained eight separate standards or risk areas:[23]

- Learning from experience;
- Response to major clinical incidents;
- Advice and consent;
- Health records;
- Induction, training and compliance;
- Training and competence;

19 S. Walker T111.149–150
20 AB/20, WS0000055538 and WS0000055555
21 AB/9 WS0000055070
22 Bartholomew WS00000546967, para 37; AB/21 WS0000055583; CLO000001183 *Closing submissions of the NHSLA*, para 113
23 AB/2 WS0000054746–747

- Implementation of clinical risk management;
- [Implementation of] clinical care; [and where relevant, the management of care in trusts providing mental health services].

15.33 There was no consideration of clinical governance.

15.34 The assessment of compliance required a trust to demonstrate compliance with the criteria and to produce evidence of achievement in each area. In demonstrating compliance, a trust would be able to select the evidence to support this: "The onus is on the member Trust to demonstrate compliance with risk management criteria. It is the responsibility of the member Trust to draw to the attention of the Assessor to achievements in each of the subject areas. The time available to the Assessor will not permit detailed searching for information."[24]

15.35 The assessment process would always include a visit but this would vary in length depending on the level against which the trust would be assessed. Level 1 assessments would take one day, whereas assessments at level 2 would take two days and at level 3, two and a half days. Levels 2 and 3 would involve a request for documentary evidence prior to the visit as well as interviews with clinical staff during the onsite visit and a visit to a clinical area to review evidence in practice.[25]

15.36 The outcome of the assessment was a determination of whether a trust had reached one of three levels:

- Level 1 criteria were representative of "basic elements of a clinical risk management framework";
- Levels 2 and 3 were described as more demanding and the standards document stated that "Many are concerned with the implementation and integration into practice of policies and procedures, monitoring them and acting on the results. These levels also require staff to have a good understanding of clinical risk issues."[26]

15.37 The grading would be dictated as follows:

- For level 1, a trust would have to achieve 75% of the total score available for level 1 criteria in every standard. The discount for compliance at this level was 10%;
- For level 2, 90% of the score for level 1 and 75% of the score available for level 2 would have to be achieved in every standard. The discount for compliance at this level was 20%;

24 AB/2 WS0000054758, para 7.15
25 AB/2 WS0000054756–58
26 AB/2 WS0000054755

- For level 3, 90% of the scores available in levels 1 and 2 would have to be achieved as well 100% of the score available for level 3 criteria in every standard. The discount for compliance at this level was 30%.[27]

15.38 The Trust was free to choose the level for which it wished to be assessed. Every trust had a mandatory assessment every two years. However, they were free to contact the NHSLA and request an assessment sooner if they wished to be assessed to a higher level.[28]

The 2004 assessment of the Trust

15.39 In June 2004, the Trust was assessed as having attained level 3, meaning that it was judged to have scored 100% against all criteria, apart from two scores of 90% at levels one or two of one standard ("induction, training and competence").[29]

15.40 The assessor's report, as was the NHSLA's normal practice, did not explain why compliance was found, but was an exception report offering a narrative only in areas where it was thought improvement was required. In one case, "Learning from Experience", the assessor had noted that the Trust had:

> *... demonstrated in action plans, minutes of meetings and policy documents that changes had been made, however the evidence did not, in some instances, confirm whether the actions had been implemented.*
>
> *It is suggested that prior to the next assessment the Trust implements a process of audit to monitor the effectiveness of the implementation of the actions taken to determine their effectiveness. The results of such audits should then be discussed and reviewed at the relevant meetings and any amendments defined in the minutes.*[30]

15.41 Despite this finding, the assessor awarded a score of 100%.

15.42 As Counsel to the Inquiry pointed out in his closing submissions, there has been ample evidence of poor incident reporting practice.[31]

27 AB/2 WS0000054755; WS0000054753
28 AB/2 WS0000054753
29 AB/3 WS0000054923
30 AB/3 WS0000054928, para 1.2.2
31 CL0000002720, *Counsel to the Inquiry closing submissions*, Chapter 20 – The NHS Litigation Authority, para 45

15.43 The criteria relevant to incident reporting which were assessed were as follows:

Table 15.1: Assessment criteria of the Trust relevant to incident reporting

Standard/criterion		Level	Score
1.1.1	Patient adverse incidents and near misses are reported in 50% of all specialties	1	20
1.2.2	There is evidence of management action arising from patient adverse incident reporting	2	20
1.2.3	Patient adverse incidents and near misses are reported in 100% of specialties	2	20
1.2.5	Examples of two changes which reduce risk as a consequence of complaints can be demonstrated	2	10
1.3.2	Examples of five changes which reduce risk as a consequence of complaints can be demonstrated	3	10

Source: NHSLA standards assessment 2004[32]

15.44 The Trust was awarded a score of 100% for these criteria. The assessor noted:

> *... the Trust provided some excellent evidence to demonstrate that most grades of staff from all areas of the Trust are fully committed to reporting incidents. It was found that staff feel very supported in doing so, however during discussions it was highlighted that there is some disparity between departments with regard to the feedback that staff receive from the incidents which they have reported.*[33]

15.45 The more specific findings in relation to these criteria revealed further reservations:

- There was limited evidence that all grades of medical staff were actively involved in incident reporting;
- The evidence did not in some instances confirm that actions in action plans, minutes of meetings, and policy documents had been implemented. The Trust was advised to audit the effectiveness of the implementation of actions before the next assessment.[34]

15.46 As is apparent from this consideration, and it was accepted by the NHSLA, that an assessment of compliance with their standards is not a mark of perfection, and points for action can be and often were offered even where compliance with a standard was accepted. It was intended to be an indication that there was sufficient evidence of compliance. The point was made that some of the assessor's documentation was not available and therefore the precise nature of instances where scope for improvement was found cannot now be identified.[35]

32 AB/2 WS0000054793
33 AB/3 WS0000054924
34 AB/3 WS0000054928, page 6, paras 1.1.1 and 1.2.2
35 CLO0000001165–166, *Closing submissions of the NHSLA*, p17, paras 61–63

15.47 Therefore, it is not clear on what basis a score of 100% compliance could have been awarded, although there has been no suggestion from the NHSLA that the assessor was not following the required system of assessment.

15.48 There was some surprise within the Trust itself at the award of level 3 status. Trudi-Anne Williams, Deputy-Director of Clinical Standards at the Trust from February 2004 to February 2007, told the Inquiry:

> *... this somewhat surprised me on what I found. The incident reporting systems within the Trust were not as robust as one would expect at level three. Whilst there was a system for incident reporting, it was not really monitored by anyone, or did not appear to be monitored by anyone, at least not on a regular basis. It took a long time for documents to get on the system and nobody monitored trends or looked at actions ... I felt the view in the Trust about CNST level there was 'god knows how we have got this?'*[36]

15.49 Thereafter, the Trust was able to rely on this award of level 3 status in demonstrating apparent compliance with some of the Annual Health Check's standards. Ms Williams explained, referring to the declaration in relation to standard C1a (which included incident reporting):

> *I had a conversation with the previous director of clinical standards and it was, "Oh, we've got CNST so we know that one's compliant. We're all right with that one". So it was almost like there was no debate or discussion around it because there was something there, you know, for her to gain her assurance from. ... So that rather than scrutinising it individually, you would take something that was already existing, already in place or that you'd submitted for something else, because there was a lot of crossover between all the different assessments.*[37]

15.50 She admitted that this claim was inconsistent with what she knew about the incident reporting at the Trust, but considered that she was insufficiently experienced to challenge this at the time:

> *... the specific reason I remember this one is obviously because this was an area that I was ultimately involved in and, you know, through incident reporting and the clinical risk manager and myself were concerned that we hadn't got any evidence to back this assessment on, that we were actually just submitting a declaration on the basis of somebody's say-so, really. So we had a private discussion about that, you know, too – around our personal concerns about it, but as I say, you know, I wasn't significantly experienced enough to challenge that at the time.*[38]

36 Williams WS0000019179, paras 25–26
37 Williams T133.71–72
38 Williams T133.72–73

2006–2007 changes to risk management standards and assessment

15.51 Following a review of the standards, a revised set was produced and piloted in the assessment of 60 organisations in 2006–2007. A final version was published in 2007–2008.[39] A clinical governance standard was introduced. The following levels were developed:

- Level 1 required the documentation of effective risk management processes and policies (Policy);
- Level 2 required implementation of the processes and policies (Practice);
- Level 3 required monitoring by the trust of its compliance with the systems and policies and acting on the findings (Performance).[40]

15.52 The time taken for an assessment was reduced to two days and the number of assessors reduced from two to one. The intention was to make the assessment less stressful and presumably less burdensome for trusts.[41] Another feature designed to reinforce this was that the evidence on which trusts were assessed was to be chosen by them and restricted to a limited number of examples showing compliance.[42] Ms Bartholomew explained that it would have been impossible for assessors to look everywhere, and at everything, and that some evidence of compliance enabled a balanced judgement to be made:

> *Although the assessor might ask to see additional evidence or ask questions to clarify certain points, the implementation of the approved documentation is judged principally, if not entirely, by reference to the documentary material provided.*[43]

15.53 The assessor would have limited time to look at what was produced. An assessor would have only 12 minutes to spend on assessing each of 50 criteria. In the case of the assessment of the Trust in 2007, it appears that 630 references were provided to more than 100 different documents. This must have meant that only a superficial examination of some of the material was possible. Ms Bartholomew agreed that this could only provide a "snapshot".[44]

15.54 As in previous years, a discount on premiums was offered for the award of all three levels, even level 1. Ms Bartholomew explained the reasoning for this, including level 1, where assessment was solely document based:

> *... because organisations need formal written documents to communicate standard organisational ways of working which help to bring consistency to day to day work which can improve quality and safety ...*

39 Bartholomew WS0000054689, para 13
40 AB/9 WS0000055021, para 5.4
41 AB/10 WS0000055136, no. 20
42 Bartholomew WS0000054696, para 33
43 Bartholomew WS0000054696, para 34; and WS000005407, para 52
44 Bartholomew WS0000054704–705, paras 54–55

NHSLA standards are claims based and documentary evidence of processes and systems is often important in the management of claims.[45]

15.55 Apparently, the NHSLA had had adverse experiences in litigation because of trusts failing to have the required documentation.[46]

15.56 The new standards were divided into:

- Governance;
- Competent and capable workforce;
- Safe environment;
- Clinical care;
- Learning from experience.

15.57 The levels can be illustrated by looking at those for incident reporting:

Table 15.2: Clinical governance assessment criteria

	Level 1 – Policy	Level 2 – Practice	Level 3 – Performance
6	The organisation has approved documentation which describes the process for ensuring a systematic approach to the analysis of incidents, complaints and claims on an aggregated basis.	The organisation can demonstrate implementation of the approved documentation which describes the process for ensuring a systematic approach to the analysis of incidents, complaints and claims on an aggregated basis.	The organisation can demonstrate that there are processes in place to monitor the overall effectiveness of the approved documentation which describes the process for ensuring a systematic approach to the analysis of incidents, complaints and claims on an aggregated basis.

Source: NHSLA[47]

15.58 At this stage, it is worth noting that each of these levels look at compliance in terms of a preset standard of process. None look at outcome measures, nor indeed specific event incidents or seriousness.

45 Bartholomew WS0000054695, para 31
46 Walker WS(3) WS0000053684, para 17
47 AB/9 WS0000055054, p43

The 2007 assessment of the Trust

15.59 The assessment of the Trust took place in October 2007. It had applied for an assessment at level 2 and was successful. Its scores were:[48]

Governance	9/10
Competent and capable workforce	8/10
Safe environment	9/10
Clinical care	9/10
Learning from experience	10/10

15.60 The score for governance was achieved even though the assessor found that the governance strategy had only been ratified the previous month and the Executive Governance Group had only met three times. The assessor was unable to say that the governance structures were "embedded".[49]

15.61 Ms Bartholomew explained that this was a necessary compromise because the standards were so new that an organisation would not necessarily have been able to supply a full year of evidence and as a result this was treated as a transitional phase.[50]

15.62 Another criterion – supervision of staff in medical training – was in reality not assessed at all because it had been agreed that NHSLA would rely on assessments made by the Postgraduate Medical Education and Training Board (PMETB) and the Conference of Postgraduate Medical Deans.[51] These organisations then did not supply the expected information. The NHSLA did not require its assessors to carry out their own assessment of this, but to award a score indicating compliance automatically.[52] This was a period during which, as evidenced by the concerns of Dr Turner, the Trust's supervision of trainees was substandard (see *Chapter 18: Medical training*, *Chapter 2: The Trust* and *Chapter 8: Performance management and the strategic health authorities*).

15.63 The assessor gave full marks to the Trust for "learning from experience". The evidence considered consisted of a penicillin reaction report and "examples" of a Serious Untoward Incident investigation.[53] It seems unlikely that the assessor was given sight of the investigation report into the case of Mrs Gillian Astbury, which evidenced a dysfunctional incident

48 AB/15 WS0000055482, p5
49 AB/15 WS0000055485, p8
50 Bartholomew WS0000054706, para 64
51 See www.copmed.org.uk
52 AB/15 WS0000055487, p10; Bartholomew WS0000054706, para 65
53 AB/14 WS0000055456

management system. The incident had not been reported in the Trust's internal system or uploaded to the National Patient Safety Agency (NPSA).

15.64 Ms Bartholomew was shown the Gillian Astbury report and advised the Inquiry that it may well not have caused the Trust to be "failed" even if it had been seen:

> *It may not have caused them – in fact probably wouldn't have caused them to fail the particular criterion because they have followed their process for doing an SUI, as far as I can tell from what's here. And also it's only one criterion in the whole of the standards. So even if it had caused them to fail the incident reporting standard because there had been perhaps other instances where the assessor had had concerns ... It would not have caused them to fail the overall assessment. However, if the assessor had read a report of this nature, then I would have hoped the assessor would have highlighted their concerns in the assessment report and possibly with the litigation authority itself.*[54]

15.65 The award of level 2 to the Trust has to be compared with the findings made the following year by the Healthcare Commission (HCC) about the state of governance and other matters during the same period as covered by the NHSLA assessment. Ms Bartholomew had reviewed the assessment in light of the HCC report and concluded that it had been properly conducted:

> *The assessor was simply interested in considering whether processes had been or were being put in place to address the examples that had been given and did not assess the outcomes of these processes.*[55]

15.66 She was challenged on this, but maintained that the Trust had been correctly assessed at level 2 in accordance with NHSLA standards:

> *Q: But the overall effect of what has happened is that the NHSLA, which clearly has a compelling interest in detecting high risk organisations, has gone in ignorance of perhaps the highest risk organisation there was at the time?*
>
> *A: I think that's quite a harsh criticism because, as I say, we look at our standards, and some of the things that have come out through what has happened at Mid Staffs are not things that are covered by our standards. Some of the issues to do with staffing levels, we've discussed earlier we don't look at, and a number of the other areas we don't look at. So, yes, I accept that we didn't notice this but based on the evidence we saw, against our prescribed standards, the trust was a level 2.*

54 Bartholomew T112.47–48
55 Bartholomew WS0000054709, para 73

Q: Forgive me, I think you may misunderstand the point of the questions I'm asking, which is not to seek to say your assessor was rubbish or that ... there was a lack of responsibility. I'm seeking to look at, with the knowledge that we now have, as to whether this is an effective system or not, and what I'm asking you to address is whether, given what we know about the matters contained here, a system which, for instance, does not look at staffing levels can be described as effective.

A: I think it's effective because it's very clear that it doesn't look at staffing levels. We – we look at the approach that organisations take to managing risk, and in the main we actually are able to determine whether that approach is what we would expect to see.[56]

15.67 Stephen Walker told the Inquiry he did not think there was anything within the NHSLA's remit which could have led them to detect the position at the Trust:

... I am absolutely convinced that there is nothing within our remit which could have led to us picking it up or preventing what happened from happening; nor is there now.[57]

15.68 Even if they had discovered the true position, there was a limited amount that the NHSLA could have done, he said. It would have been "pointless" to expel the Trust from the scheme as that would run the risk of patients not being compensated if there was no indemnity cover.[58]

Conclusions on the NHS Litigation Authority

15.69 The NHSLA is not a regulator and is principally concerned with the management of claims made against the NHS and in reducing the risks of exposure to such claims. However, it has been given the associated task of setting risk management standards for its members and the monitoring of compliance with those standards.

15.70 Currently, its requirements are imposed on almost all NHS providers as very few foundation trusts have so far chosen to seek alternative forms of indemnity against claims, although they are free to do so. The effectiveness of any steps the NHSLA may take in promoting the improvement of risk management and any associated benefits for patient safety, are therefore dependent on it continuing to have near universal coverage of providers.

56 Bartholomew T112.51–53
57 S Walker WS(3) – WS0000053691, para 54
58 S Walker T111.187

15.71 The Department of Health (DH) and the NHS Commissioning Board (NHSCB) should consider what steps are necessary to require all NHS providers, whether or not they remain members of the NHSLA scheme, to have and to comply with risk management standards at least as rigorous as those required by the NHSLA.

Risk management reports

15.72 Risk management reports are a potentially useful tool for scrutiny of a trust's compliance with risk management requirements. They are also an indicator of the existence of poor practice. It would be unfortunate if the frequency with which these are produced is significantly reduced. As some form of running record must be retained on each claim in order for these reports to be produced, the NHSLA could consider the development of a relatively simple database containing the same information.

15.73 These reports would be potentially useful to the Care Quality Commission (CQC) as part of its Quality Risk Profile (QRP), although the weighting given might be low for cases relating to incidents that had occurred some time ago, but perhaps not where there was a longstanding apparent failure to remedy deficiencies that had been identified through this process. As the interests of patient safety should prevail over the narrow litigation interest under which confidentiality or even privilege might be claimed over such reports, consideration should also be given to allowing the CQC access to these reports.

Clinical Negligence Scheme for Trusts standards

15.74 The development of risk management standards is a considerable advance on the position which preceded the birth of the NHSLA. Risk management was then in its infancy and there was no standard approach to it. The introduction of standards was undoubtedly a positive step.

15.75 The formulation of the standards has changed for the better. They now include provisions regarding clinical governance, an area where serious concerns can arise. It would be desirable for requirements with regard to staffing levels to be introduced. It is not for the NHSLA to mandate levels for skills of staff, but it could reasonably require trusts to have regard to evidence-based guidance and benchmarks where these exist and to demonstrate that effective risk assessments take place when changes to the numbers or skills of staff are under consideration. Measures of this nature are included in the proposed standards for A&E, but similar requirements should be included in the general standards. They will have to be broader in application and possibly less specific, but the NHSLA could usefully lead a consideration of how staffing benchmarks and guidance could be developed in a systematic way.

15.76 The part of the structure which causes concern is the definition of the three levels and, in particular, level 1. Given the essential contribution effective risk management can make to patient safety, it should not be regarded any longer as acceptable for a trust merely to prove it has policies: trusts should be expected to be able to show not only that they have implemented such policies but are using them thoroughly, effectively and throughout the organisation. In other words, the norm should be considered to be what is now level 3.

15.77 The NHSLA is right to consider the removal of financial incentives for level 1 and they should be severely reduced in amount and in the time for which any incentive will be offered for level 2. The incentives at levels below level 3 should be adjusted to maximise the motivation to reach level 3.[59]

15.78 Quite rightly, the NHSLA publishes its assessments. A further incentive may be to explain, in terms the public are more likely to understand than at present, the implications for patient safety and quality of care of a level 1 rating in particular, and to describe what is not known about the risk management at a trust as a result.

15.79 The NHSLA shares some of its risk management information with the NPSA in the context of patient safety and lessons learned by allowing access to material in order to look at claims for learning purposes.[60]

15.80 The NHSLA traditionally shared information with the predecessors of the CQC annually, but the CQC have requested that information be provided on a more timely basis. As a result, the NHSLA now highlight concerns as they arise by phone or email.[61] As to information being examined from the CQC prior to NHSLA assessments of trusts, Alison Bartholomew, NHSLA Risk Management Director, told the Inquiry that there would be no routine policy of an NHSLA assessor examining CQC reports in relation to the trust they are assessing.[62] In relation to recent notifications from the NHSLA to the CQC, the Inquiry was informed that, aside from regulators being informed of trusts dropping to level 0 in the NHSLA's assessment, there had not been any specific concerns raised with the CQC in the last year.[63]

15.81 At the same time, it is important that the public is left in no doubt as to the limitations of the significance that can be placed on CNST ratings. The evidence clearly shows that it has frequently been proposed as an indicator that safe care is being delivered whereas that is not the case.

59 CLO000001185, *Closing submission of the NHSLA,* para 121
60 Bartholomew WS0000054722, para 115
61 Bartholomew WS0000054722, para 114
62 Bartholomew T112.61
63 Bartholomew T112.62–63

Clinical Negligence Scheme for Trusts assessments

2004

15.82 The 2004 CNST assessment awarded the Trust level 3 status which it was able to retain for three years. It relied on this status as evidence of compliance for some HCC Annual Health Check standards, and was understood in a local newspaper to confirm that the Trust was one of the safest hospitals in the country.

15.83 There were elements of the assessment process that were not entirely satisfactory. This is not to criticise the assessor whose assessment has effectively been endorsed by the NHSLA, and therefore can be accepted as complying with their expectations. However, exception reports are a weak basis for demonstrating or justifying the basis of an assessment of compliance. It would have been helpful for the evidence supporting the determination to have been listed, and for brief reasons to have been given. This would have added little to the burden of the assessor and given a much better picture of what a determination of compliance actually meant in each case. While no doubt perfection could not reasonably be demanded before compliance was accepted, the terminology used by the assessor in relation to incident reporting does not suggest that compliance existed throughout the Trust. Albeit faintly, the report contains the echoes of some of the problems of which more detail has now been exposed. The evidence of Trudi-Ann Williams is consistent with this view. It suggests that, contrary to the arguments of the NHSLA, the assessment of compliance left something to be desired. It allowed the Trust to be awarded the highest level, without being able to demonstrate compliance throughout the organisation. It also allowed it to escape further scrutiny for three years, even in relation to the points on which action was required by the assessor.

15.84 It was not the responsibility of the NHSLA that the level 3 status was, in practice, abused by the Trust to support its declaration of compliance with the relevant HCC standard, but it was a weakness of the system that this could happen.

2007

15.85 The failure of the NHSLA assessment in 2007 to detect the woeful state of various parts of the organisation, which was at this time, in retrospect, presenting a very high level of risk, suggests either that the assessment was wrong or that the system, whether in its standards or the system of assessment, was not up to the task set for it. The NHSLA have expressed no concern that the assessment was not in accordance with their expectations. The standards appear on the face of them to cover areas found defective by the HCC, although staffing numbers in particular was a criterion absent from these standards. For example, it is difficult to believe that the Trust had "implemented" its incident reporting policies given what is now known about the system at the time. It is therefore more than likely that it was the process of assessment which was not adequate. The net it cast had very large holes through which the Trust, which was in reality not compliant, could pass. Only limited areas were chosen to be

looked at, and the Trust could chose its own evidence, with no attempt to look at other areas of the assessor's choice being required. This is not to say that this was something the NHSLA could have been expected to predict and cater for at the time. It had very properly embarked on an exercise to improve the previous system and in some respects had done so. The nature of levels had been clarified, and the standards expanded. What was weakened was the process of assessment, but this was consistent with general policy expectations of the time of lightening the administrative burden.

15.86 The retrospective reaction of the NHSLA to the failure of the 2007 standards to detect the Trust as a problem as expressed to the Inquiry was puzzling. If an assessment of risk management is incapable of identifying the sort of risks directly relevant to its exposure to negligence claims, let alone any wider interests of patient safety, it has to be asked what the purpose of the assessment process was.

Changes since 2007

15.87 Little has changed in the standards since 2007, but the NHSLA has reintroduced a more rigorous assessment method. They have reverted to assessment by two assessors and 12 months of evidence showing compliance is required.[64]

15.88 As of July 2011, some 23 trusts out of a total of 180 had a level 3 rating whereas there were 40% who remained at level 1.[65] The Trust was not among them. It was assessed for level 1 in October 2010 and failed because its documentation was not in order.[66] The NHSLA is concerned at the number of trusts at level 1 and is considering removing the discount that has been offered for trusts at that level.

15.89 Since the NHSLA witnesses gave evidence, a performance and capability review of the NHSLA has been published.

15.90 In April 2011, the insurance broker and risk advisor Marsh Limited published the *NHSLA Industry Report*, the result of a study commissioned by the DH into the role and remit of the NHSLA.[67] The report found that, in general, the NHS risk pooling scheme over which the NHS provides was, "a valid concept, which is widely accepted and endorsed", and that, "its stewardship and administration by the NHSLA has been effective". However, the report found that:

64 Bartholomew WS0000054712, para 80
65 Bartholomew T112.81–82
66 Bartholomew WS0000054712, paras 78–79
67 *NHSLA Industry Report* (April 2011), Marsh, www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_132413.pdf

There are some areas where the NHSLA does not achieve optimum performance and there are a number of practices that are commonly applied by commercial insurance organizations that would lead to better performance in these areas.[68]

15.91 In relation to risk management, the report concluded that:

... the risk management standards are, in general, highly regarded and have introduced a consistent framework for risk management and have helped to elevate clinical risk management to a board level agenda.

However, there are opportunities to increase incentives for Trusts to improve their risk management standards and claims experience. There is also a lack of leverage for the NHSLA to impose penalties on poorly performing Trusts. In addition, Marsh have found that the current risk management system does not utilise the large and unique data set that the NHSLA holds in order provide wider analysis of claims over a greater range of clinical specialities.[69]

15.92 The following recommendations were made:

- Develop the current risk management standards to reflect more risk-specific specialties such as A&E and general surgery so that contributions more accurately reflect the risk profile of the trust, with greater use of the data and more feedback to trusts to ensure lessons are learnt;
- Greater application of discounts and penalties to reflect claims experience and compliance with claims-reporting protocols to incentivise best practice within trusts;
- Increase the number of risk management standards to 4 or 5, with a removal of the contribution discounts for the basic level of risk management (level 1);
- Development of an online tool to increase transparency and allow trusts to see how changes in risk management criteria and procedures will affect their contribution levels;
- There should be greater alignment between the NHSLA standards and the approaches adopted by other bodies, in particular Monitor and the CQC;
- Risk assessments should be more regular and proportional to the size of the trust.[70]

Conclusions and recommendations were also set out in relation to the "claims management, legal and IT" and "strategic and cultural" functions of the NHSLA.

68 *NHSLA Industry Report* (April 2011), Marsh, page 1, www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_132413.pdf
69 *NHSLA Industry Report* (April 2011), Marsh, page 2, www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_132413.pdf
70 *NHSLA Industry Report* (April 2011), Marsh, pages 2–3, www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_132413.pdf

15.93 In January 2012, the DH published a response to the *NHSLA Industry Report*, setting out its reaction to each of the report's recommendations, which were either accepted, rejected or placed under consideration.[71]

15.94 In a letter to all trusts on 30 July 2012, Catherine Dickson, the current NHSLA Chief Executive announced that: "our current approach to risk management standards should be revised so that the standards are focused on outcomes and that the assessment process should be less burdensome to our members". As a result of this, a full schedule of assessments will not be carried out in 2013–2014 in order to facilitate a process of consultation and pilot schemes leading to the institution of new standards and a new assessment process.[72]

15.95 The NHSLA should, as part of its review of its CNST standards and means of assessments, review the deficiencies in risk management now identified to have been present at the Trust between 2005 and 2009 and consider how to change the standards and the assessment of compliance to enable such deficiencies to be detected by its processes.

15.96 The NHSLA should make level 3 the minimum requirement for entitlement to a reduced premium.

15.97 The NHSLA should make more prominent in its publicity an explanation comprehensible to the general public of the limitations of its standards assessments and of the reliance which can be placed on them.

National Clinical Assessment Service

15.98 In April 2001, the National Clinical Assessment Authority was established in response to recommendations made by Professor Sir Liam Donaldson, then Chief Medical Officer, in the report *Supporting Doctors, Protecting Patients*. It started life as a separate arms-length body of the DH, before being merged with, and made a division of, the NPSA in 2005 and being renamed the National Clinical Assessment Service (NCAS). Following the recent reforms, it is due to be transferred to the NHSLA.[73]

15.99 NCAS is an advisory body that advises on the most appropriate actions to be taken by a healthcare organisation that is concerned about the practice of a doctor, dentist or pharmacist. It aims to do so in a manner that is both fair to the practitioner and effective in protecting patients. It is not a regulator. It covers the whole of the United Kingdom and offers its services to NHS organisations, the independent health sector and to the defence services.

71 *NHSLA Industry Review: Department of Health Response* (January 2012), DH, www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_132411.pdf
72 Letter to trust chief executives from Catherine Dickson (30 July 2012), NHSLA, www.nhsla.com/NR/rdonlyres/BA35DBA6-35B2-46F7-8E11-39D2FB833D6B/0/RiskManagementServicesJuly2012.pdf
73 This was publicly announced on 8 August 2012 by an NCAS press release: www.ncas.nhs.uk/news/national-clinical-assessment-service-to-become-part-of-nhs-litigation-authority/ (accessed 22.08.12)

15.100 It receives referrals for its services at the rate of about 1,000 cases a year, or one in 200 practising doctors. About half of all NHS organisations are working with NCAS at any one time. Given the volume of work, it has very few staff: 16 part time advisers. This represents a major reduction on the numbers previously employed during the period of the Inquiry's terms of reference.[74]

15.101 NCAS's aim is to become involved in cases of concern as early as possible and it encourages informal contact before the formal making of a referral. NCAS has been making progress in persuading trusts to do this. At the organisation's inception, a third of cases referred to it had already been referred to the GMC, whereas the proportion now is 3%.

15.102 Professor Alistair Scotland, the former Director of NCAS, did not accept that NCAS's role delayed the proper progress of cases to the GMC. He claimed that the "correct cases" are getting to the GMC earlier.[75]

15.103 One of the functions of NCAS is to support the employing organisation by reviewing the doctor in four domains:

- Knowledge and skills – the individual's technical ability;
- Health and well-being – how the individual's health and well-being affects their work;
- Behaviour – how the individual typically acts and interacts with others at work;
- Work context – the effect of the team and the organisation on the individual.[76]

15.104 In a small proportion of cases, it offers a performance assessment of the doctor, which includes in-depth interviews by panels of assessors with a view to creating an action plan to address the concerns about the doctor. The purpose is, if reasonably possible, to rehabilitate doctors with problems to enable them to provide a safe and effective service and to avoid losing the expensive resource a doctor represents.[77]

15.105 Professor Scotland made it clear that NCAS focuses on individuals rather than organisations but suggested that its work could be used to pick up indications of organisations in trouble. The criteria used to identify organisations which may have been in difficulty were:

- Volume of cases referred from a particular organisation being either very high or very low;
- A bulge of cases referred over a short space of time;
- Clustering of cases within specialties or departments;
- A major problem with a practitioner, specialty or department;

74 Scotland WS0000048168-169, paras 12–13
75 Scotland T102.132
76 Scotland WS0000048175, para 33
77 Scotland WS0000048176, paras 35, 37 and 40

- An organisational response to NCAS's involvement falling short of what would be expected of an NHS organisation.[78]

15.106 When NCAS sees such a development in a trust it can offer assistance and on occasion has sent a team of assessors to provide support to the employer.[79]

National Clinical Assessment Service contact with the Trust

15.107 Between 2002 and March 2009, the Trust referred 11 cases to NCAS, seven of them during the period of the Inquiry's terms of reference. All were doctors, of whom six were surgeons. The Trust's referral rate was towards the upper end of the scale by comparison with other organisations, but it was not an outlier and the high referral rate could not of itself be considered cause for concern about the Trust.[80]

15.108 A cluster of cases occurred in November 2009 following the 2009 Royal College of Surgeons (RCS) peer review report (see *Chapter 2: The Trust*). Surgeons had also been referred after the earlier 2007 RCS report. In neither case had the Trust shared the report with NCAS. Professor Scotland thought this should have happened:

> *With hindsight, … the organisational response of Mid Staffordshire over several years in its involvement with cases which it referred to us fell short of that which would be expected of an NHS organisation. In summary, the response was tardy and incomplete, with long delays in acting on our advice. These problems were exacerbated by the frequent change in the key personnel at the Trust who were charged with … managing these cases.*[81]

15.109 At the time there had been no indicator, said Professor Scotland, that the Trust itself was a cause for concern, although the comment noted above might give pause for thought about that assertion.

15.110 Professor Scotland considered that NCAS could have a contribution to make in detecting and preventing another Stafford, but suggested that a number of changes were required for that to be made more likely. He considered that a requirement to refer "problem" doctors should be required of trusts in the CNST standards and a professional duty of cooperation with NCAS imposed on doctors.[82] He also recommended that a duty of candour be imposed on trusts to oblige them to disclose all relevant material to NCAS.[83]

78 Scotland WS0000038185, para 60
79 AS/10 WS0000048472, para 6
80 Scotland WS0000048189, paras 70–73
81 Scotland WS0000048192, para 79
82 Scotland WS0000048197, para 91.4
83 Scotland WS0000048193, paras 85–86

Conclusions on the National Clinical Assessment Service

15.111 NCAS performs a valuable service in assisting healthcare employers with the challenges presented by doctors whose competence, or conduct, gives cause for concern. It is a service which has the potential to reduce the sort of challenge that Mr Sumara, the Trust's former Chief Executive, and Dr Obhrai, the Trust's former Medical Director, have suggested exists in resolving disciplinary issues concerning doctors expeditiously and fairly. It is a service, however, which will work most effectively when a referral is made with the consent of both parties. It is in the public interest that efforts are made to retain the services of doctors in whom the State has invested significant resources in training, so long as patient safety and public confidence in the service and the profession is not prejudiced.

15.112 With regard to Professor Scotland's suggestions of how NCAS could contribute to the detection of problem organisations, it may be unwise to encourage it to take on such a role. There are already multiple organisations with that specific responsibility and it could create additional confusion to add another one to the list. It would also be difficult for NCAS to assume such a role while at the same time maintaining the confidentiality it rightly sees as essential to the assistance it gives in individual cases. So far as securing the full and open cooperation of and disclosure from organisations seeking its help, there seems to be no reason why NCAS cannot simply require these as a condition of its assistance. The incentive would be that a failure of the NCAS process in an individual case because of non cooperation or non disclosure could put the trust in a very difficult position in relation to any subsequent disciplinary proceedings against its employee.

15.113 With regard to its contact with the Trust, it appears that there was nothing striking about the pattern of referrals. Given that NCAS had no responsibility for the monitoring of organisations or their governance, it would have required something extremely dramatic in individual cases for it to be suggested that it ought to have taken some form of action about it. For good reason, respecting the necessary confidentiality for its work, the Inquiry has not looked into the individual cases or what information NCAS was given about them.

Summary of recommendations

Recommendation 91

The Department of Health and NHS Commissioning Board should consider what steps are necessary to require all NHS providers, whether or not they remain members of the NHS Litigation Authority scheme, to have and to comply with risk management standards at least as rigorous as those required by the NHS Litigation Authority.

Recommendation 92

The financial incentives at levels below level 3 should be adjusted to maximise the motivation to reach level 3.

Recommendation 93

The NHS Litigation Authority should introduce requirements with regard to observance of the guidance to be produced in relation to staffing levels, and require trusts to have regard to evidence-based guidance and benchmarks where these exist and to demonstrate that effective risk assessments take place when changes to the numbers or skills of staff are under consideration. It should also consider how more outcome based standards could be designed to enhance the prospect of exploring deficiences in risk management, such as occurred at the Trust.

Recommendation 94

As some form of running record of the evidence reviewed must be retained on each claim in order for these reports to be produced, the NHS Litigation Authority should consider development of a relatively simple database containing the same information.

Recommendation 95

As the interests of patient safety should prevail over the narrow litigation interest under which confidentiality or even privilege might be claimed over risk reports, consideration should also be given to allowing the Care Quality Commission access to these reports.

Recommendation 96

The NHS Litigation Authority should make more prominent in its publicity an explanation comprehensible to the general public of the limitations of its standards assessments and of the reliance which can be placed on them.

Chapter 16
The Health Protection Agency

Key themes

- The Health Protection Agency (HPA) had concerns about the Trust's management of hospital acquired infections in 2006, 2008, and 2009.
- While such concerns were shared with the Primary Care Trust (PCT), they were not, before 2009, escalated directly to the Strategic Health Authority (SHA), which it was assumed would be informed by the Primary Care Trust (PCT). Extant guidance required such concerns to be escalated formally by the HPA to the SHA.
- Guidance about sharing concerns with Monitor was unclear and following the Trust's acquisition of foundation trust (FT) status the HPA did not make it aware of such issues.
- The HPA's concerns were not shared with the Healthcare Commission (HCC).
- More robust arrangements for sharing infection control concerns with regulators and performance managers are required.

Introduction

16.1 A narrative of the Health Protection Agency's (HPA's) interaction with the Trust appears in *Chapter 1: Warning signs* and *Chapter 2: The Trust*.

16.2 This chapter offers a short description of the HPA, its constitution, staffing and role as an advisory organisation (rather than a regulator or manager), and considers its specific projects in national surveillance of MRSA, *Clostridium difficile* (*C. difficile*), glycopeptide resistant enterococci (GRE) and its Surgical Site Infection Surveillance Service (SSISS). HPA's dealings with other bodies are also examined.

16.3 Finally some consideration is given to the lessons to be learned from the Stafford experience for the future in this important field.

The constitution and functions of the Health Protection Agency

16.4 The key functions of HPA, as far as they relate to the Inquiry, concern the control of healthcare associated infection (HCAI). The HPA was created in 2003 and was intended to act as a source

of national expertise and provide key services at national, regional and local levels in a range of specified areas of health protection. It took overall responsibility for the surveillance of infectious diseases and was designed to play a key role in the provision of a service for the prevention and control of infectious diseases in the population.[1]

16.5 HPA is a statutory, independent, executive non-departmental body, which is sponsored by the Department of Health (DH).[2] It was originally regulated by the Healthcare Commission (HCC) from 2005 to 2009 and is now regulated by the Care Quality Commission (CQC).[3]

16.6 HPA's powers are set out in the Health Protection Agency Act 2004. Section 2(1) provides that its functions relating to health are:

> *a) the protection of the community (or any part of the community) against infectious disease and other dangers to health;*
>
> *b) the prevention of the spread of infectious disease;*
>
> *c) the provision of assistance to any other person who exercises functions in relation to the matters mentioned in paragraphs a) and b).*[4]

16.7 Section 4(1) of the Act allows HPA to do any of the following in exercising its functions:

> *a) engage in or commission research;*
>
> *b) obtain and analyse data or other information;*
>
> *c) provide laboratory services;*
>
> *d) provide other technical and clinical services;*
>
> *e) provide training in relation to matters in respect of which the Agency has functions;*
>
> *f) make available to any other body such persons, materials and facilities as it thinks appropriate;*
>
> *g) provide information and advice.*

16.8 Section 4(2) allows the HPA to do anything it considers appropriate to facilitate these functions and section 7(1) gives the HPA a general power to publish information it receives and the advice it gives. Section 5 of the Act also places a duty of mutual cooperation on the HPA and other bodies which exercise health functions.

1 McCracken WS(Provisional) HPA0001000003, para 4
2 McCracken WS0000023707, para 8
3 McCracken WS(Provisional) HPA0001000004, para 7
4 McCracken WS(Provisional) HPA0001000006, para 17

The Health Protection Agency's role in practice

16.9 The HPA's role is primarily advisory and is carried out by:

> *Providing expert advice and information to the public, the Government, other agencies, local authorities and people working in healthcare.*[5]

16.10 Following the outbreaks of *C. difficile* at the acute trusts for Stoke Mandeville, and Maidstone and Tunbridge Wells, the precise role of the HPA in relation to primary care trusts (PCTs) and strategic health authorities (SHAs) was set out in guidance from the DH in 2007. This stated (emphasis added):

> *It has been agreed that the DH will take the lead on delivering a programme of work to reduce HCAI and the* ***role of the HPA is to reduce episodes of HCAI by giving advice and support to the NHS organisations in preventing and managing HCAIs****. Formal responsibility for performance management of acute trusts and NHS bodies lies with the Primary Care Trust (PCT) and Strategic Health Authorities (SHA).*[6]

16.11 The role of the HPA in escalating concerns about a trust in light of this guidance was explained by its Chief Executive Justin McCracken in his evidence to the Inquiry (emphasis added):

> *The guidelines also state that the HPA will* ***formally escalate concerns to performance managers at the SHA and PCT*** *(and as high as the Department of Health if necessary) when bodies have inadequate infection control systems, fail to appropriately address incidents and outbreaks or fail to respond to the HPA's advice. Operationally this means that close working and good professional relationships are essential between the HPA and key players in trusts, PCTs and SHAs to ensure that national and local guidance is implemented.*[7]

16.12 Between 2003 and 2008, the operational day-to-day work of health protection units (HPUs) was specified by memoranda of understanding with individual PCTs, which provided that HPA would supply a named consultant who would take the lead and liaise with each hospital trust and provide support with the investigation and management of outbreaks of infectious diseases. The HPA would also advise the PCT of significant deficiencies in its services. The memoranda set out that the PCT's role would include providing or commissioning NHS services, such as hospital control of infection and isolation facilities, promoting and monitoring good antimicrobial prescribing practice and encouraging the reporting of infection to the HPA.[8]

5 McCracken WS(Provisional) HPA0001000003, para 4
6 JM/7 HPA0001000349
7 McCracken WS0000023711, para 24
8 McCracken WS(Provisional) HPA0001000011, paras 41–44

16.13 From 2008 the memoranda were replaced by framework specifications,[9] which set out that HPA would provide specialist health protection support to PCTs and SHAs and in return would expect PCTs and SHAs to commission and deliver public health services to national standards and allow the HPA to influence public health service decisions.[10]

16.14 As at March 2010, the HPA operated from 69 locations and had almost 4,000 staff. It comprises four specialist centres and also has a Local and Regional Services (LaRS) Division organised into nine regions in England, each with a regional director and made up of a total of 26 local HPUs.[11]

16.15 Delivery of public health provision in the West Midlands region of the HPA is the responsibility of the Director for the West Midlands. West Midlands North HPU has responsibility for the Trust and includes within its remit a population of 1.6 million people across Shropshire and Staffordshire, five PCTs and four acute trusts.[12]

16.16 The Government announced in July 2010 that it intended to abolish the HPA as a statutory organisation and transfer its functions to the Secretary of State for Health.[13]

National surveillance of healthcare associated infections by the Health Protection Agency

16.17 The HPA is responsible for national surveillance of three HCAIs in the NHS and independent healthcare organisations. These are:

- MRSA bacteraemia;
- *C. difficile* infection;
- GRE bacteraemia;
- E. coli;
- Methicillin-sensitive *Staphylococcus aureus* (MSSA) infection.

16.18 The primary purpose of this surveillance has been to document longer-term trends in incidence and to track progress towards achievement of defined targets for disease reduction. It does not, therefore, focus specifically on trends from individual providers. Although HPA coordinates this data nationally, it is dependent upon the provision of information data by trusts.[14] As part of the increased national focus on HCAIs, the reporting of MRSA (since 2001), GRE (since 2003), and *C. difficile* (since 2004) has been mandatory.[15]

9 JM/14, HPA0001000526
10 JM/14a, HPA0001000545
11 McCracken WS(Provisional) HPA0001000005, para 10
12 McCracken WS(Provisional) HPA0001000005, para 13
13 McCracken WS(Provisional) HPA0001000004, para 6
14 McCracken WS(Provisional) HPA0001000009, para 35
15 McCracken WS(Provisional) HPA0001000009, para 36

16.19 The data collected by the HPA would be provided to other bodies including the HCC, PCTs, SHAs, Monitor and the DH by access to a web-based data capture system for the mandatory surveillance of these three HCAIs.[16] Returns from trusts to the HPA of such information were provided quarterly, then monthly from October 2005 for MRSA, and from April 2007 for *C. difficile*.[17]

16.20 Locally, since 2005, the HPA West Midlands Regional Epidemiology Unit has produced a series of HCAI bulletins providing an overview of HCAI surveillance in the region. These have been based on data collected from the mandatory surveillance of the three key HCAIs. These evolved from quarterly bulletins to monthly bulletins in May 2008 and were used to assist the HPUs in the region in providing advice relating to infection control. Since 2008, these bulletins have also been shared electronically with trusts and PCTs in the West Midlands, as well as the SHA. However, they have not bee not shared with the HCC, any other national bodies or the national centres of the HPA.[18]

16.21 The HPA remained reliant on the accuracy of the data on HCAIs provided to it by the trusts.[19] To help ensure this, from July 2007 all trust chief executives were required to sign off the HCAI data submitted to the HPA on the fifteenth of each month to confirm its accuracy. In order to further verify this, the HPA would carry out routine comparison of mandatory HCAI data against voluntary laboratory data to identify any significant discrepancies. Mr McCracken stated he understood that no discrepancies were identified between HCAI surveillance data and that from the Trust during the period relevant to the Inquiry.[20]

16.22 Mr McCracken explained the role of the HPA's monitoring of HCAIs and its limitations in relation to data from individual trusts:

> *It is not designed in order to drive the management of healthcare-associated infection in individual hospitals, it is not a real-time system. It is a historical system, and the provision of information to drive infection control in hospitals is the responsibility of the hospital, using the real-time information which they have, and which will ultimately in summary form lead into or feed into the national systems. And our support to hospitals, in terms of management of infection control, is through – principally through their infection control meetings and using the real-time information which they provide to us in that forum.*[21]

16.23 He also gave evidence that, with the exception of *C. difficile* infection data, none of the mandatory surveillance data indicated that the Trust was an outlier.[22]

16 McCracken WS0000023712, para 28
17 McCracken WS(Provisional) HPA0001000009, para 36
18 McCracken WS0000023717, paras 47–8
19 McCracken T101.15
20 McCracken WS0000023715, paras 42
21 McCracken T101.16
22 McCracken WS(Provisional) HPA0001000016, para 77

Surgical Site Infection Surveillance Service

16.24 SSISS was set up in 1997 and was transferred from the Public Health Laboratory Service (PHLS) to the HPA when the latter was established. The service aims to enhance the quality of patient care by providing a standardised methodology for hospitals to collect data and compare their rates of surgical site infection (SSI) against a benchmark rate for defined categories of surgery, and to use this information to review and guide the clinical process.[23]

16.25 The HPA reviews the data collected on a quarterly basis to assess whether the incidence in a given hospital for the most recent period or for the past four surveillance periods is above the ninetieth percentile as a "high outlier" or below the tenth percentile as a "low outlier" for that category of surgery. Those hospitals identified as either high or low outliers are contacted by letter and asked to investigate possible reasons for this. Following this communication, the respective regional epidemiology unit works with the hospital to provide support and ensure satisfactory investigation is carried out. Communication continues until the HPA is satisfied with the response given by the trust in question.[24]

16.26 As with data in relation to HCAIs, the HPA is reliant on the accurate reporting of SSI data from hospitals and has no means of independently verifying the data which it receive.[25] There are no routine discussions between the HPA and the CQC over SSI data.[26]

16.27 The Trust has participated in the SSISS since 2000 and has been found to be over and above the minimum requirements for this mandatory surveillance. The Trust was identified as a low outlier for quarterly surveillance periods in July to September 2008 and July to September 2009. Letters were sent communicating this to the Trust in March 2009 and July 2010 and on both occasions the Trust reassured the HPA that the surveillance protocol was being adhered to. Following the second letter in July 2010, the HPA was informed that one case had been reported, which gave the Trust an infection rate of 0.9% compared with the rate in England of 1.2%. As a result, no further action was taken.[27]

Interactions between the Health Protection Agency and the Trust

C. difficile 2006

16.28 In 2006, a "period of increased incidence" of *C. difficile* was identified at the Trust, although no outbreak was declared at the time. This was against a broader national increase in *C. difficile* cases and was not viewed as a unique occurrence by HPA staff at the time. HPA analysis of

23 McCracken WS(Provisional) HPA0001000010, para 38
24 McCracken WS0000023718, para 51
25 McCracken WS0000023718, para 51
26 McCracken WS0000023712, para 29
27 McCracken WS(Provisional) HPA0001000014, paras 66 and 78

the 2006 rates of infection comparing the Trust with other trusts showed that it was not an outlier in 2006.[28]

16.29 During this period the HPA identified a number of issues concerning infection control at the Trust and these were incorporated into an action plan. It included the following points:

- Improvement in antibiotic prescribing;
- Improvement in the availability of surveillance data within the Trust;
- The need to update staff;
- Closer working between ward nurses and infection control staff;
- Ad hoc audits.[29]

16.30 The HPA provided input into the action plan but it was emphasised that this was a Trust action plan, responsibility for implementation of which lay with the Trust and which would have been monitored by the Trust and its performance managers. Over a period of months, the number of *C. difficile* cases was reduced to levels seen in other similar Trusts.[30]

C. difficile 2008

16.31 This is dealt with in detail and referenced in *Chapter 1: Warning signs*. Between 14 April and 14 July 2008, eight patients were found to be suffering from *C. difficile* on ward 11. Dr Musarrat Afza, the HPA's local Consultant in Communicable Disease Control (CCDC), advised the Trust during this period on managing this infection. In the circumstances Dr Afza urged the Trust to declare an outbreak but was told that a robust action plan was under way. Dr Afza did not agree with this assessment and noted that the Trust had not detailed isolation and cohorting arrangements for infected patients in ward 11 and that a number of points were missing from the action plan, including requirements to clean shower chairs and commodes with bleach rather than general purpose detergent, and the disinfection of mattresses after incontinence. Dr Afza told the Inquiry that there were other steps which the Trust would have been highly recommended to take such as the closure of the affected ward to new admissions and the isolation of infected patients. She felt that there should have been ribotyping of the infection to establish whether there were links between cases. In addition, it emerged that the Trust could not provide an isolation ward as there was no available space for one.

16.32 Dr Afza was told of another case of *C. difficile* on the same ward on 18 July 2008 and at this point the ward was closed to admissions and an outbreak declared. It appeared that the outbreak had been brought under control by the end of July 2008; however, Dr Afza remained unhappy with the Trust's reaction and felt that the incident had not been accorded a sufficient

28 McCracken WS0000023724, para 76
29 McCracken WS0000023724, para 80
30 McCracken WS0000023725, para 82

sense of urgency by the Trust and that sufficient regard had not been given to her advice. She therefore had concerns that this gave rise to a similar risk of an outbreak occurring in the future.

16.33 A further cluster of *C. difficile* did in fact occur in September and October 2008, when four cases occurred in ward 7 within 11 days. Again ribotyping was not undertaken and so it was not possible to say whether cases were linked and constituted an outbreak. Dr Afza felt the same level of concern over this as she did in relation to the July outbreak.

16.34 The Trust's apparent unwillingness to declare an outbreak (or to undertake ribotyping to enable such a declaration) and its lack of dedicated isolation facilities were causes of concern to the HPA and no doubt would have been valuable information for the West Midlands Strategic Health Authority (WMSHA), the HCC and Monitor.

16.35 The 2007 guidance cited by Mr McCracken (see above) required formal notification to the performance manager. However, despite this the HPA did not raise these concerns with the HCC and viewed such a step only as a last resort.[31] Concerns were instead raised directly only with the Trust.[32]

C. difficile 2009

16.36 In January 2009, there was a further *C. difficile* outbreak on ward 8 where there were four cases diagnosed within 19 days. An outbreak control team meeting took place on 27 January 2009.[33]

16.37 Dr Afza had a number of concerns over the Trust's handling of this outbreak:

- A commode audit, which had been taken the day before the 27 January meeting, recorded a figure of 0%, indicating a complete failure in compliance with cleaning standards.
- The Trust was relying on agency staff due to staff shortages, despite staff shortages being raised as an issue in July 2008. It was felt that agency staff would be likely to be unfamiliar with the Trust and its routines and would need appropriate supervision from permanent staff.
- Although a root cause analysis was being proposed by the Trust this was being carried out too late to be effective.
- A recent audit had shown only 30% adherence to audit standards in relation to patient prescription charts. This meant that in seven out of ten cases patient prescription charts failed the audit, which in itself had the potential to contribute to an increase in *C. difficile* infections, which are known to be associated with prolonged use of antibiotics. It was felt

31 McCracken WS0000023721, para 66
32 McCracken WS0000023712, para 29
33 Afza WS0000041489, paras 75–77

that this issue required greater clinical leadership from the Trust, that it had not been given sufficient priority and that the Trust should have had an antibiotic pharmacist in place.
- Infection control required commitment from all members of staff at the Trust and the Infection Control Team needed support from senior management yet Dr Afza did not see sufficient evidence of leadership in this area.
- An outbreak meeting had not been called. Such a meeting would have involved multidisciplinary attendance, including members of the Estates Management Team responsible for cleaning the hospital as well as members of the HPA and PCT.
- Despite Dr Afza raising concerns at the lack of a dedicated isolation facility at a Steering Group meeting on 26 January 2009, the Trust had failed to address these concerns.[34]

16.38 This outbreak continued for longer than the previous incidents, lasting from January until March 2009. Dr Afza felt that this outbreak was therefore more serious than the previous ones, and that there were underlying issues at the Trust which remained unaddressed.[35]

16.39 Dr Afza emphasised that the position changed with the appointment at the Trust of Julie Hendry as Interim Director of Nursing and Midwifery at the end of 2009, and subsequently of Colin Ovington, as Director of Nursing, and that the appropriate importance had since been attached to the infection prevention and control process.[36]

16.40 Mr McCracken shared Dr Afza's view that there had been a reluctance on the part of the Trust to declare outbreaks of *C. difficile*. He was unable to give a reason as to why this may have been the case, but stated that it could have been due to the fear of creating adverse publicity and attention from performance managers and commissioners.[37]

Dealings between the Health Protection Agency and other bodies

Primary Care Trust and Stategic Health Authority

16.41 Mr McCracken stated that, through its membership of the Trust's Steering Group on Infection and Prevention Control from September 2007, the PCT was aware of the HPA's concerns in relation to the Trust.[38] He also stated that the HPA escalated its concerns to the Regional Director of Public Health in March 2009.[39]

16.42 Dr Afza, in her evidence to the Inquiry, stated that as a commissioner the PCT was "very, very well aware of our concerns" over isolation facilities in 2008.[40] However, she also highlighted the limitations in the HPA's influence in the circumstances:

34 Afza WS0000041490, paras 79–91
35 Afza WS0000041492, para 88
36 Afza WS0000041498, para 115
37 McCracken T101.32; T101.134
38 McCracken WS0000023733, para 113
39 McCracken WS0000023733, para 114
40 Afza T101.115

With regards to the advice given to the acute trust, … when that has been the case, I have raised it with the acute trust and, you know, in the presence of the PCT. With the advice – with regards to giving advice to the PCT, which we do in terms of infection control matters in the community, … I can't remember an occasion where we would have given an advice and … they would have said, "We're not going to take it". They may – it is a matter for the organisation themselves to consider our advice, and, you know, do the prioritisation within their resources and decide whether they can take our advice on board or not. But I think that's the minimum which we expect of the organisations, that once.[41]

16.43 When asked why she had not been able to achieve what she had wanted between July 2008 and March 2009, Dr Afza made clear that she was limited in what she could do:

My role is to give the professional advice, which I did. My role was to pursue it and to try and, you know, achieve the results, in terms of keeping it on the agenda and expecting the trust to do something about it. And I think I did all of those actions. It is not within my powers – the Health Protection Agency has got no statutory, regulatory or commissioning role, so it wasn't within our remit to be able to influence this agenda any further. The PCT was very well aware of the situation in the trust regarding isolation facilities.[42]

16.44 The SHA, unlike the PCT, was not represented in any of the Trust's meetings on infection control prior to March 2009, and therefore was unlikely to have picked up any concerns from that source.[43] On 11 March 2009, following the publication of the HCC report, in reply to a request from Dr Rashmi Shukla of the WMSHA for a digest of HPA's involvement with and advice given to the Trust, an email from the Acting Director of the West Midlands North HPU summarised for her the HPA's concerns about the Trust and its handling of the 2008–2009 episode. These included its reluctance to recognise an outbreak requiring high level leadership and coordination, a lack of robust information provision, and certain actions taken to control the outbreak.[44] Apart, possibly, from some telephone conversations in February and early March 2009, this appears to have been the first formal communication of concern to the SHA.[45] It has been advanced on behalf of HPA, that even though the SHA was not formally written to in 2008, it would have been aware of HPS's concerns via the PCT.

16.45 The HPA's concerns were also expressed in a briefing note from the HPA to the Regional Director of Public Health dated 25 March 2010, this time following the publication of the first inquiry's report. This note laid out retrospectively the HPA's concerns over the Trust's conduct in relation to HCAIs in 2006, 2008 and 2009. The HPA's concerns for this period were summarised as follows:

41 Afza T101.117
42 Afza T101.157–8
43 Afza WS0000041496, paras 109–110
44 JM/26 HPA0001000683
45 Afza T101.166

The single major issue which remains, and which could be traced back to the root of almost every issue raised, was a lack of integrated, effective institutional communication. This varies from cleaning staff not fully appreciating the key value of their role, to reports of some consultants failing to provide appropriate leadership through recognition of the valid concerns of others, upon whom the operations for which they are responsible are dependent.[46]

16.46 In his oral evidence, Mr McCracken expressed that by March 2009 it was felt as though both the HPA and the PCT were banging their heads against a brick wall[47] in relation to advice given to the Trust, but that HPA did not have the power to direct the Trust to follow its advice. HPA instead depended on others to bring about change.[48]

16.47 The concerns identified by HPA about the Trust clearly fell into the category which the 2007 guidance suggested required formal escalation to the SHA. This does not appear to have happened until, at the earliest, after the publication of the HCC report.

Healthcare Commission

16.48 The Inquiry was told that the HPA did not have any communication with the HCC in relation to the periods of increased incidence of *C. difficile* in 2006, 2008 and 2009.[49] According to Mr McCracken, the HPA would only raise concerns directly with the regulator as a last resort and it was not felt that this was necessary in relation to the Trust.[50] Mr McCracken explained in his oral evidence:

The focus of our attention with the Trust was to help and support them in managing this situation, the increased incidence, as you refer to it, of the C. Diff. That was the focus of our attention. We were aware that the Primary Care Trust, which commissions the work from the Trust and also has responsibility for performance managing, were also aware of this situation. And it would, from our point of view, not have been normal now, for us to bring to the attention of the regulatory authorities the increased incidence of healthcare-associated infection.[51]

16.49 As a result, the HPA input into the HCC investigation of the Trust was limited to a single telephone interview with Dr Afza and the HPU Director conducted on 17 August 2008 in the course of its investigation of the Trust.[52] The interviewer asked about the increased incidence of *C. difficile* in 2006, the action taken and why an outbreak was not declared. The Inquiry

46 McCracken WS99 WS0000023730; JM/25 HPA0001000673
47 McCracken T101.56
48 McCracken T101.54
49 McCracken WS0000023712, para 29
50 McCracken WS0000023721, para 66
51 McCracken T101.42–3
52 McCracken WS0000023716, para 45 and 91–3

was told that the HPU Director answered from memory as best he could, but stated that he would need to review the infection control minutes to answer specific questions. As far as the interviewees could recall, there was no discussion of the 2008 outbreak, which was ongoing at the time. The HPA interviewees offered to supplement their answers if required, but received no further communication from the HCC.[53]

16.50 Dr Afza confirmed this and that whilst the PCT and SHA received notification of serious untoward incidents (SUI) at the Trust and the PCT received information from attending the Steering Group meetings at the Trust, the HCC was not present at these meetings.[54] It is, therefore, apparent that other than the telephone interview in August 2008, there was no contact between the HPA and the HCC in relation to the Trust.

16.51 Dr Afza accepted that with hindsight it could be said that the omission to inform the HCC of the HPA's concerns was a deficiency, but suggested that a clear protocol was required to ensure clarity about what needed to be reported.[55]

Monitor

16.52 In relation to Monitor, Mr McCracken told the Inquiry that, although there had been meetings with Monitor in August and November 2007 which discussed how to improve operational relationships and sharing of information, there were no further national-level meetings between the HPA and Monitor. He was not aware of any other interaction with Monitor in relation to any particular Trust at the time relevant to the Inquiry.[56]

16.53 Despite accepting that because it was a foundation trust Monitor was the regulator responsible, Mr McCracken explained the lack of interaction with them in the following way:

> *The role that we had agreed with the Department of Health in 2007, following the Healthcare Commission report into the Stoke Mandeville outbreak, did set out that we should play a proactive role. It – it reclarified our role but it made it clear we should take a proactive role in advising trusts. And I believe we played a very proactive role in advising Mid Staffs in this occasion. And it also made clear that we should raise our concerns, if we didn't feel they were being acted upon, with the primary care trust and the strategic health authority. We did that. The role did not specify that we should be involving the regulator. And with a focus on seeking to protect patients in real time, we naturally focused on the bodies that we believed could actually have some influence over the trust, in terms of improving the situation in the hospital at the time.*[57]

53 McCracken WS000002327–8, paras 91–93
54 Afza WS0000041478, para 30
55 Afza T101.168
56 McCracken WS0000023721, paras 62–65
57 McCracken T101.55

16.54 Given the Trust's FT status from February 2008 and Monitor's role as its regulator, it would seem strange that there was contact with the SHA in 2009 but not Monitor when the SHA did not have a regulatory function in relation to the Trust at that time. However, as Mr McCracken stated, this was in accordance with guidance from the DH, which the HPA followed. Dr Afza's explanation for there being no communication with Monitor was that it was understood that it was concerned with finance and that the quality of care at a foundation trust was still a matter for the commissioners, the performance managers and probably the HCC.[58]

The future

16.55 The HPA is to be abolished[59] and its relevant functions transferred to Public Health England (PHE), with effect from April 2013.[60] PHE is to be an executive agency of the DH and its Chief Executive, Duncan Selbie, will be accountable to the Secretary of State.[61] There will be a publicly appointed Chair, whose role will be to lead an advisory board and to offer support and advice to the Chief Executive. The current Chair of HPA has been appointed Acting Chair of PHE. The Chair will also provide assurance on strategy and oversight of organisational governance.

16.56 The health protection function will be undertaken by a health protection directorate under the leadership of PHE's Medical Director. Amongst its priorities will be:

> *Ensuring the highest possible standards of advice and support to local authorities, the NHS, the Government and international partners.*[62]

16.57 There will also be a knowledge and intelligence directorate under the leadership of the Chief Knowledge Officer. Its priorities will include:

> *Delivery of a new national evidence and intelligence service that supports transparent assessment of need; tracks performance and progress against key outcomes.*

16.58 Its goals will include:

> *Effectively promoting an evidence-based approach to public health practice across the system.*[63]

58 Afza T101.167
59 Health and Social Care Act 2012, section 56
60 Public Health England's Operating Model Factsheets (December 2011) DH
61 Structure of Public Health England, 26 July 2012. DH gateway ref 17957 https://www.wp.dh.gov.uk/healthandcare/files/2012/07/PHE-structure.pdf
62 Structure of Public Health England, 26 July 2012. DH gateway ref 17957 https://www.wp.dh.gov.uk/healthandcare/files/2012/07/PHE-structure.pdf p6
63 Structure of Public Health England, 26 July 2012. DH gateway ref 17957 https://www.wp.dh.gov.uk/healthandcare/files/2012/07/PHE-structure.pdf p11

16.59 In his evidence, Mr McCracken stated that the retention of HPUs as a key component of the public health system would enable PHE to deploy specialist expertise locally.[64]

Conclusions

16.60 The HPA is not a regulator, and it is not intended that PHE will be one either. It is, however, clear from the interaction of the HPA with the Trust that its staff will often have detailed knowledge of trusts' systems for controlling HCAIs and of how effective these are.

16.61 Mr McCracken told the Inquiry that HPA's ability to provide oversight or assurance was limited:

> *The HPA is not resourced to 'fill a gap' in infection prevention and control at a poorly performing trust, rather than adding the 'complementary' skill set envisaged by the guidance. The CCDC who has to deal with such a situation can only do so if they involve partner organisations and escalate concerns. It is imperative that trusts have effective and expert leadership for infection control as well as a culture and embedded systems that make infection control 'everybody's business', and that trusts do not rely on external leadership and intervention.*[65]

16.62 In spite of those limitations, the HPA often has information of considerable value to those responsible for commissioning or regulating healthcare providers. If HPA or its successor does not share the information in its possession with those who have the power to require change, there is a potential for serious risks to patient safety being left unremedied: providers may fail to act on HPA's advice, and external agencies can remain in ignorance of the problem. It is, therefore, imperative that the HPA and its successor communicate to the relevant commissioners and regulators any information in their possession which, in their opinion, indicates the existence of a risk to patient safety which is not receiving the required action by those responsible.

16.63 Applying that standard, which is consistent with the contemporary guidance, the HPA had concerns about the management of infection control at the Trust, which it should have, but did not, share promptly with the SHA. There seems to have been an assumption that contact with the PCT was sufficient for this purpose.

16.64 In fairness, following the Trust's authorisation as a foundation trust, there was room for doubt as to whether the SHA was the appropriate organisation to which to report concerns about a foundation trust, but no approach was made to Monitor, in part because the guidance was not clear, and in part on the grounds that it was believed only to be concerned with financial issues. No information was offered to the HCC about the concerns raised in 2006, 2008 or

64 McCracken WS0000023735, paras 120–3; McCracken T101.77
65 McCracken HPA0001000026, provisional statement, para 107, p24

2009, and at the single interview the HCC conducted with an HPA representative in 2008, less than satisfactory detail was given.

16.65 Therefore, with the exception of the PCT, no external agency was alerted as they should have been to the extent of the concerns harboured about the management of infection control. There was insufficient consideration given to the importance of communication with regulatory and supervisory bodies in order to ensure that relevant information pertinent to patient safety was properly disseminated and discussed, and appropriate action considered.

16.66 Looking to the future, there appears to be no reason why PHE will not assume all the current functions with regard to HCAIs currently undertaken by HPA, and it is assumed this will be the case. Further consideration is nevertheless required about the extent to which information about HCAIs in hospitals is shared with other agencies and with the public. The HPA approach has been that dissemination of information to the public is a matter for the provider trust to decide on. HPA is concerned that requiring a greater degree of information sharing by HPA or PHE could undermine its relationship with providers.[66]

16.67 With regard to information sharing with other agencies, Dr Afza made the reasonable point that clarity of the scope of any sharing obligation and proportionality are required:

> *I believe ... more clarity is needed, with the multiplicity of organisations responsible for regulatory and performance managing roles. It's very difficult to think of how many bodies you need to report to. In your daily working life, you will end up doing nothing but communicate to this, that and other organisation. So there needs to be clear outline for how matters need to be escalated and who is responsible for that.*[67]

16.68 The public are entitled to have accurate information about the incidence of HCAIs in hospitals. In making a choice of where to go for treatment this may be highly relevant knowledge. A well run trust should have no fears about disseminating figures showing its performance in this area. It should be able to explain any outbreaks and what action it is taking to address them. It should be able to demonstrate that it is able to manage such issues in accordance with the relevant standards of practice. Whilst such information provision may principally be the responsibility of each hospital provider, given the expertise and knowledge available within HPA and its successor, it would be of benefit to the public if they coordinated the collection, analysis and publication of information.

66 McCracken T101.33–40
67 Afza T101.170

16.69 Where the HPA or its successor becomes concerned that a provider is not addressing adequately and in accordance with accepted standards issues of infection control, it should share its concerns with all agencies which are in a position to require or initiate remedial action. These will include the relevant commissioners, the CQC and, where the concern relates to a foundation trust, Monitor.

16.70 The creation of PHE offers an opportunity to revisit the support that health protection staff can offer to local authorities and other agencies in relation to local oversight of healthcare providers' infection control arrangements. Local representatives and interested and committed members of the public could be an invaluable resource for monitoring the performance of providers in this field. Health protection staff could support this role with information and perhaps training.

Summary of recommendations

Recommendation 106

The Health Protection Agency and its successor, should coordinate the collection, analysis and publication of information on each provider's performance in relation to healthcare associated infections, working with the Health and Social Care Information Centre.

Recommendation 107

If the Health Protection Agency or its successor, or the relevant local director of public health or equivalent official, becomes concerned that a provider's management of healthcare associated infections is or may be inadequate to provide sufficient protection of patients or public safety, they should immediately inform all responsible commissioners, including the relevant regional office of the NHS Commissioning Board, the Care Quality Commission and, where relevant, Monitor, of those concerns. Sharing of such information should not be regarded as an action of last resort. It should review its procedures to ensure clarity of responsibility for taking this action.

Recommendation 108

Public Health England should review the support and training that health protection staff can offer to local authorities and other agencies in relation to local oversight of healthcare providers' infection control arrangements.

Chapter 17
The National Patient Safety Agency

Key themes

- The National Reporting and Learning System (NRLS) is an important information resource, the use of which is challenged by reporting being voluntary, variability in reporting practices, and the numbers of incidents reported.
- The National Patient Safety Agency (NPSA) received a large number of incident reports from staff at the Trust raising issues of staff shortage. While these were analysed for the Inquiry, the NPSA lacked the capacity to undertake such work routinely.
- The NPSA did not share information about "cause for concern" letters with regulators or performance managers. Following the publication of the Healthcare Commission (HCC) report the NPSA did exceptionally communicate with the Care Quality Commission (CQC) about a concerning pattern of reported incidents at the Trust.
- The NPSA did not routinely analyse the incident reports received by reference to the relevant provider trust to identify patterns of concern.
- From April 2010 the CQC has been given access to all reports of moderate and severe incidents and deaths.
- In common with other providers, the Trust failed to implement a significant proportion of Patient Safety Alerts within the required time. There is a lack of clarity of responsibility for follow up of implementation.
- The functions of the NPSA have been transferred to the NHS Commissioning Board (NHSCB) and are therefore not managed by a separate independent entity.

Introduction

17.1 The National Patient Safety Agency (NPSA) was described in the Department of Health (DH) document *Building a Safer NHS for Patients* (2000) as:

> *A new independent body, which will implement and operate the* [national system for learning from error and adverse events] *with one core purpose – to improve patient safety by reducing the risk of harm through error.*[1]

Constitution and function

17.2 The NPSA was established as a Special Health Authority, and was subject to the direction of the Secretary of State for Health.[2] It was not a regulatory body, had no regulatory powers and was not responsible for monitoring performance of individual organisations. The NPSA did not have powers to investigate any individual organisation, but instead shared its information with the NHS regulatory and oversight bodies, such as strategic health authorities (SHAs), primary care trusts (PCTs), the Care Quality Commission (CQC) and Monitor.[3]

17.3 Between 2001 and 2005, the agency focused solely on patient safety. In 2005, the NPSA was reconfigured, following its merger with the National Clinical Assessment Agency and the Central Office for Research Ethics, into three separate parts: the patient safety division, the National Clinical Assessment Service (NCAS) and the National Research Ethics Service (NRES).

17.4 When the NPSA began in 2001, it consisted of a handful of staff. From 2005 onwards, the organisation grew and employed 300 people at its peak in April 2011, with approximately 100 of those working within the patient safety division. However, from that point on, the function of NSPA was reduced in anticipation of its abolition, along with a concomitant reduction in the size of the organisation.[4] The key functions of the NPSA relating to patient safety transferred to the NHS Commissioning Board on 1 June 2012.

17.5 This chapter focuses on the patient safety division of the NPSA.

Establishment

17.6 The NPSA was established following a report by the former Chief Medical Officer, Professor Sir Liam Donaldson, in 2000, entitled *An Organisation with a Memory*.[5] The report stated that where failures in NHS care occur:

1 Suzette Woodward WS0000044964, para 6
2 NPSA WS(Provisional) – NPSA00000000002, para 1.1
3 NPSA WS(Provisional) – NPSA00000000005, paras 1.4–1.5
4 Suzette Woodward WS0000044964, para 7
5 SW/2 WS0000045028

... they can have devastating consequences for individual patients and their families, cause distress to the usually very committed health care staff involved and undermine public confidence in the services the NHS provides. In addition, the cumulative financial cost of adverse events to the NHS and to the economy is huge. Most distressing of all, such failures often have a familiar ring, displaying strong similarities to incidents which have occurred before and in some cases almost exactly replicating them. Many could be avoided if the lessons of experience were properly learned.[6]

17.7 The report identified that NHS reporting and information systems at the time provided "a patchy and incomplete picture of the scale and nature of the problem of serious failures in healthcare". Whilst inquiries and incident investigations following the most serious adverse events would periodically call for lessons to be learned, the report concluded that "the evidence suggests that the NHS as a whole is not good at doing so".[7]

17.8 Although a number of mechanisms were identified for gathering data on failures in healthcare, there was no consensus on what to report, no proper linkages between the different reporting systems and confusion over their purpose.[8] The report also noted a "blame culture", which acted as a deterrent to the reporting of adverse events and near misses, and served to obscure systemic problems in favour of targeting individuals. There was also little self-appraisal, reinforcing the negative effects of the culture.[9]

17.9 The report, therefore, recommended the introduction of a mandatory reporting scheme for adverse healthcare events and specified near misses. The report stipulated that the scheme should:

- Be rooted in sound, standardised, local reporting systems, building on and developing the current local adverse-event reporting system;
- Adopt as the basis for reporting the concepts of an adverse healthcare event and a healthcare near miss;
- Devise and publish a set of detailed standardised categorisations of different types of adverse event and reportable near miss, and specify the format in which they should be reported;
- Adopt standardised computer software;
- Set out clearly the channels for reporting and the locus of responsibility for ensuring reports are made;
- Be comprehensive in its coverage, incorporating all NHS organisations which deliver healthcare along with GPs and dentists treating patients in primary care, and care provided on behalf of the NHS in private facilities;

6 SW/2 WS0000045036, para 1
7 SW/2 WS0000045037, paras 4–5
8 SW/2 WS0000045117–8, para 5.4
9 SW/2 WS0000045120, para 5.8

- Be mandatory for both organisations and individuals;
- Be run by an independent body, which is perceived as neutral by healthcare staff.[10]

17.10 This recommendation led to the development of the National Reporting and Learning System (NRLS), which was to be managed by the NPSA.

National Reporting and Learning System

17.11 Introduced in 2003 to 2004, and fully implemented in 2005, the primary purpose of the NRLS is for national learning: to identify risks at a national level that require action to be taken across the whole of the NHS.

How the system works

Reporting via the internal reporting systems of trusts, or direct reports by individuals via the internet

17.12 There are three routes by which healthcare staff can report a patient safety incident to the NRLS:

- By completing and sending a form to the clinical governance or risk management department of a local organisation, which in turn uploads the information on to the NPSA's NRLS reports web page; 98% of patient safety incidents are reported in this way;[11]
- By submitting an electronic form to the NPSA website directly;
- By completing a specialty-based form set up for a specialist group, such as anaesthetists or GPs.

17.13 The service is designed so that patients and the public can also report a safety incident, either through the local organisation (via the Patient Advisory Liaison Service) or directly through the NPSA website.

17.14 The NRLS was set up to be an anonymous system, with the names of all parties and any identifiable data removed before a report is placed on the database.[12]

Numbers of reports and rate of reporting

17.15 At the time the Inquiry heard evidence around 3,000 incidents were reported to the NRLS each day, resulting in the receipt of over 1 million reports per year.[13] The rate of reporting has steadily increased since the introduction of the NRLS in 2003–2004.

10 SW/2 WS0000045123–24
11 NPSA WS(Provisional) – NPSA00000000013, para 3.9
12 NPSA WS(Provisional) – NPSA00000000013, para 3.6–3.10
13 NPSA WS(Provisional) – NPSA00000000014, para 3.11

Levels of harm

17.16 Under NPSA guidance, there are five levels of harm resulting from patient safety incidents: no harm, low, moderate, severe and death. Incidents originally described as "near misses" are now described as "no harm"; an example of such an incident would be when a patient was almost given the wrong drug but in fact was not. Such incidents constitute the majority of those reported to the NRLS, for example 68% nationally in 2009. The proportion of reported patient safety incidents leading to severe harm or death in the same period was less than 1%.[14]

"Never Events"

17.17 In 2007, the NPSA formulated a list of "never events" (events which should never occur in a clinical setting) in order to assist PCTs in focusing on key issues in their conversations with acute trusts. The original list of eight "never events" included wrong site surgery and wrong route administration of chemotherapy. Under the provider contract, acute trusts are required to report the occurrence of "never events", and PCTs are entitled to apply a payment sanction to the trust in response.[15] In October 2010, the list of "never events" was expanded to 25.[16]

Visits to discuss issues apparently arising from reports

17.18 During 2008, the new NPSA Chief Executive, Martin Fletcher, visited a number of front-line services to better understand the patient safety challenges they faced and how the NPSA might help. The visits involved the Chief Executive and a variety of members of the Senior Management Team for Patient Safety. The Trust was selected at random for one of these visits, and on 31 October 2008 Martin Fletcher and others met the Trust Chief Executive and the Trust Risk and Patient Safety Manager.[17]

17.19 The number of incidents reported by the Trust defined as severe harm had increased in the period April–September 2008. This increase was raised at the October meeting and, as a result, in January 2009 an NPSA reporting team visited the Trust to assist with its coding. It transpired that some of the incidents were being coded in terms of "potential harm" rather than "actual harm". Following the January visit, between April and September 2009, the number of incidents relating to severe harm and death had been reduced.[18]

Cause for concern letters

17.20 From early 2006, the NPSA began to contact particular trusts in order to follow up reports of patient deaths causing particular concern. The NPSA also flagged issues of concern arising from its monthly thematic review of incidents. Originally the follow-up was carried out by way of a phone call, but from September 2007 the follow-up took the form of a "cause for concern

14 NPSA WS(Provisional) – NPSA00000000014–15, para 3.12
15 Suzette Woodward WS0000044992–93, paras 85–87
16 Suzette Woodward WS0000045021, para 171
17 NPSA WS(Provisional) – NPSA00000000030, para 3.29
18 NPSA WS(Provisional) – NPSA00000000030, para 3.30; Suzette Woodward WS0000044999, para 106

letter". From April 2008, incidents resulting in severe harm were subjected to the same process.

17.21 The purpose of the letters of concern is to ensure that incidents where urgent local action is needed are recognised at board level in the reporting trust. This practice of sending out a letter acknowledges that not all trust medical directors will be aware of all patient safety incidents with an outcome of death (or, from April 2008, severe harm). The letters are of a standard format, signed by the NPSA Medical Director (or Deputy Medical Director) and give details enabling the trust to identify the incident in its reporting system.

17.22 Whether a letter is written in response to a particular incident is at the discretion of the person responsible for reviewing the incident. The four criteria for sending a letter of concern are:

- Abuse or neglect (actual or suspected);
- A cluster of similar incidents indicating an ongoing local failure;
- A failure to implement earlier specific NPSA guidance;
- Reports of serious underlying service problems (for example, critically low staffing levels).[19]

17.23 The NPSA does not write a letter when it appears that the incident has been reported as a "Serious Untoward Incident" to the SHA or the PCT as, in those circumstances, there is an expectation that the incident will have been recognised at board level and will be subject to external scrutiny from those bodies.

17.24 All replies are scrutinised by the NPSA Medical Director (or Deputy Medical Director). Where it is felt that the local trust medical director is aware of the incident, takes it seriously and that appropriate investigations and remedial actions are underway, they "close" the incident. The NPSA will continue to follow up the matter with the relevant medical director until assurance is received that the trust has grasped the nature of the concern and taken steps to address any patient safety issues.

17.25 All incidents of concern are registered on the NPSA database. However, no systematic review has been conducted identifying which trusts receive the most letters.[20]

The National Reporting and Learning System: A voluntary system

17.26 Although the NRLS was established to embody the recommendation in *An Organisation with Memory* that a reporting scheme should be introduced to monitor adverse healthcare, in the event NRLS was set-up as a voluntary scheme. NHS organisations can therefore choose whether to report, how much to report and what to report.

19 NPSA WS(Provisional) – NPSA00000000040, paras 3.44–3.48
20 NPSA WS(Provisional) – NPSA00000000041–42, para 3.49–3.55

17.27 The NPSA issued national guidance for patient safety incident reporting in 2004, *Seven Steps to Patient Safety*. However, the guidance is not mandatory and as a consequence there is variation across the NHS in trusts' reporting culture, and the information reported, which affects the quality of data controlled by the NPSA.[21]

17.28 Since 2007, the position has changed: the reporting of "never events" has been required by standard commissioning contracts (as mentioned above).

17.29 Dr Suzette Woodward, Director of Patient Safety at the NPSA, was not involved in the decision to introduce the NRLS as a voluntary scheme, but in her evidence to the Inquiry discussed possible reasons for the decision:

> *I suspect that those introducing NRLS at the time felt that if it was a mandatory system organisations would think of the NPSA as an NHS performance manager, rather than what it was, a learning based organisations.*
>
> *The NPSA has never been responsible for performance management or regulation of individual NHS organizations. Perhaps one of the reasons particularly why a mandatory system was not set up initially is because the NPSA did not know or have the powers to enforce mandatory reporting. Self-reporting of incidents is not designed to detect failure or problem trusts; it was designed to facilitate learning from such incidents.*[22]

17.30 Neither the role of the NPSA as a learning (as opposed to performance management) organisation, nor the absence of enforcement powers, justify the system continuing to be voluntary, particularly as part of the system is now mandatory.

17.31 The strongest argument for a reporting system being voluntary is that compulsory reporting could actually be counterproductive deterring full and candid reporting, and instead incentivising minimal, defensive reporting in accordance with the rules rather than in the interests of patient safety. However, perhaps what is more important in ensuring full and candid reporting is anonymity, as has been established in aviation through its system of incident reporting by pilots.[23]

The National Patient Safety Agency: Processing and analysis of data

17.32 The NPSA cannot scrutinise all of the 1 million incidents reported to it each year. However, as well as the issuing of cause for concern letters (as described above), every incident resulting in severe harm or death is cross-checked against the Strategic Executive Information System (STEIS), which records all Serious Untoward Incidents (SUIs), to establish whether any

21 NPSA WS(Provisional) – NPSA00000000012, paras 3.3–3.4
22 Suzette Woodward WS0000044970, para 17
23 Civil Aviation Authority WS(Provisional) WS0000077350; www.midstaffspublicinquiry.com/node/506

additional information can be gathered.[24] Other incidents, ranging from no harm to moderate harm, are aggregated for quarterly data reports, which are then published on the NPSA website and used to analyse themes and identify patterns or trends.[25]

17.33 Having analysed the data it receives, the NPSA issues several categories of guidance designed to assist the NHS as a whole and to help particular organisations learn from patient safety incidents. These include:

- Patient safety alerts, published regularly and containing information on patient safety requiring urgent action;
- Patient safety notices, published regularly and containing information requiring longer term, system-wide changes;
- Themed reports, occasionally published in-depth reports into specialist subjects;
- Cause for concern letters (discussed above);
- Quarterly data summaries (discussed above);
- Detailed feedback reports, issued to individual trusts from 2007, providing an aggregated report covering incident reporting and comparison data over the preceding six months.[26]

17.34 The detailed feedback report is the only trust-specific data analysis carried out by the NPSA.[27]

Problems with the National Reporting and Learning System

Time taken to develop the system

17.35 In 2005, the NPSA was criticised by the National Audit Office (NAO) for the time taken to set up the reporting system, which was two years longer than envisaged. Dr Woodward explained that it had taken two years (2003 to 2004) to develop the information technology behind the NRLS and a further year (2005) to test it and iron out any glitches, including harmonising the datasets of each NHS organisation. As is a common experience with IT systems, it had taken time to solve technical issues. Dr Woodward accepted that it took four to five years since its inception, for the NPSA and the NRLS system to become effective, and that "NPSA and all of the NHS were on a learning curve together".[28]

24 Suzette Woodward WS0000044979
25 NPSA WS(Provisional) – NPSA00000000016, para 3.14
26 NPSA WS(Provisional) – NPSA00000000018, para 3.16
27 Suzette Woodward WS0000044973, para 26
28 Suzette Woodward WS0000044983, paras 57–58

17.36 The technical issues may have been a contributory factor to the further criticism made in 2005 in *Safety First: A report for patients, clinicians and healthcare managers*:

> *There is little evidence that data collected through the national reporting system are effectively informing patient safety at the local NHS level. Despite the high volume of incident reports collected by the NPSA to date, there are too few examples where these have resulted in actionable learning for local NHS organisations. The National Reporting and Learning System is not yet delivering high-quality, routinely available information on patterns, trends and underlying causes of harm to patients.*[29]

17.37 The report suggested that this meant that patients could not be assured that organisations were learning from experience.

Numbers

17.38 The number of reports is so large that it raises the question of how the information can be put to use.

17.39 The statistics led Dr Woodward to describe the NRLS as "a very successful system".[30] However, Professor Sir Liam Donaldson raised a concern that the NPSA might receive more data than it could effectively deal with:

> *The number of reports received is ... huge, so that raises the question of how can we analyse them all properly. Decisions therefore need to be made as to whether we need tighter rules on incident reporting, and the distinction between local and national level reporting and follow-through.*[31]

Under-reporting

17.40 Poor nursing care is probably under-reported. Dr Woodward accepted that voluntary incident reporting was not sensitive in identifying harm arising from poor nursing care.[32] In support of this conclusion, reference was made to an academic study conducted by Ali Baba-Akbari Sari et al, which reviewed 1,006 admissions to a large NHS hospital trust, across eight specialties, between January and May 2004, comparing incident reports made at the time with a detailed *ex post facto* case note review.[33] Of the admissions analysed, the case note review identified that 136 safety incidents had occurred resulting in harm, across 110 patients. Of these, only six (5%) had given rise to an incident report. As the study notes, "this suggests that the routine

29 SW/10 WS0000045501
30 Suzette Woodward WS0000044971, para 19
31 Donaldson WS(1) WS0000070155
32 Suzette Woodward WS0000044970, para 18
33 'Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review', *BMJ* (2007 337:79), Ali Baba-Akbari Sari et al www.bmj.com/content/334/7584/79#T1

reporting system considerably under-reports the scale and severity of patient safety incidents".[34] The report concluded:

> *The routine incident reporting system may not provide an accurate picture of the extent and severity of patient safety incidents, particularly resulting in harm to patients.*[35]

17.41 Neither the study, nor its conclusions, were limited to harm arising from nursing care.

Variable practice

17.42 Guidance that is issued by the NPSA, if followed, would result in a uniform system of reporting. However, the guidance is not mandatory. As a result, the practice of different trusts varies from uploading all adverse incident reports to sharing only some. From 2007, the Trust uploaded all its incident reports.

17.43 The *Safety First* report recommended that PCTs be made accountable for ensuring that all providers had effective reporting systems and were implementing technical solutions.[36] At South Staffordshire PCT (SSPCT) it was questioned whether this could be achieved:

> *It is important to realise that the PCT in line with the rest of the NHS receives a number of guidance, reports and documents both from within and outside of the NHS. Some of these are prioritised for us ("thou shalt"), but others are left for the discretion of organisations to adopt or respond to in the light of their other priorities ("thou should") ...*
>
> *A further challenge is that many of these reports are all-encompassing statements – almost motherhood and apple pie – and take time to analyse and develop into practical activities on the ground. For example, recommendation 9 states that PCTs should "ensure" that providers have "effective" patient safety reporting systems ...*
>
> *As to how the PCT can monitor its providers have effective safety systems in place is questionable. We would actually be confirming whether our providers had a reporting system in place as opposed to assessing the effectiveness of that system.*[37]

17.44 It is clear that SSPCT did not prioritise this recommendation as its response to it was not produced until August 2007, 18 months after the *Safety First* report and 10 months after SSPCT's establishment. No doubt it had many other priorities due to the re-organisation, and may have had inadequate resources to attend to this as well as everything else.

34 'Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review', *BMJ* (2007 337:79), Ali Baba-Akbari Sari et al, "Results" and "Discussion" www.bmj.com/content/334/7584/79#T1
35 'Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review', *BMJ* (2007 337:79), Ali Baba-Akbari Sari et al, "Conclusion" www.bmj.com/content/334/7584/79#T1
36 LD/25 WS0000070833
37 Sawbridge WS0000013398–99, para 32; Sawbridge WS0000013411–12, para 78

Absence of detail

17.45 The content of the reports received by the NPSA is likely to vary depending on the author (whether that be healthcare staff or members of the public) and the mechanism by which they are submitted. The NPSA supplied the Inquiry with 940 reports submitted by the Trust through its own reporting system, all of which involved staff shortages in inpatient areas and the accident and emergency department (discussed in detail below). The following were selected as representative examples by the NPSA:

> *Ward was understaffed x2 trained Nurses & x1 Health Care Assistant – Pts were getting upset because a patient was delayed coming from them to the ward due to no one being able to prepare the room and wash the bed. At the start of the night we did have another Health Care Assistant, but he was put back onto the Site Managers books to be found somewhere else to work, due to the budget of the ward. This left the staff on the ward struggling to deal with the demands of the ward and the dependencies of the Pts.*
>
> *Unit very busy, 7 babies all on monitors, only 2 staff, no other staff available. Status Red alert on scoring system. Prior to incident one of the babies became very unwell requiring intervention therefore last incubator used, already no monitors, no emergency space. Term baby requiring resus on delivery suite, transferred to SCBU, no space, no equipment available. Member of staff had to contact x ward. Help came for short period as unable to look after all the babies. Paediatric staff unfamiliar with unit, had to use monitor off another baby, leaving this baby vulnerable, to monitor new baby oxygen levels. Infant required incubation and ventilation. Extremely difficult to care for 7 babies of which two were already unwell and requiring constant nursing intervention, and also admission of a baby requiring full resuscitation and ventilation, with limited staff and equipment.*[38]

17.46 Some of the reports submitted contained far less detail, for example:

> *On shift as the nurse in charge with five other trained members of staff and three level three patients and seven level two patients. As a result of inappropriate staffing levels patient care and safety compromised.*[39]

17.47 The reports received by the NPSA focused on a narrative account of the incident itself and its immediate consequences, rather than an analysis of contributory factors or its wider significance (although some causative information may be provided, such as the comments above regarding ward budgets).

38 SW/14 WS0000045719
39 SW/14 WS0000045731

17.48 The NRLS focuses on high-level information and does not collect investigation information such as contributory factors or causal information. No attempt is made to undertake a local "root cause analysis" of any patient safety issues raised in a report.[40]

Feedback reports

17.49 The feedback reports produced by the NPSA use a template which employs generic observations designed to assist the reader in the interpretation of the figures in the report, rather than offering the NPSA's own analysis of them. For example, the following explains a graph showing the numbers of incidents reported over different periods:

> *What does Figure 1 tell you?*
>
> *If all six months include broadly similar numbers of incidents this suggests your organisation has well established systems for regularly reporting to the NRLS, and your local risk management or clinical governance team should be congratulated. If the numbers differ dramatically over the six months, or some months show no reports submitted, it suggests your organisation has not yet established reliable systems for reporting to the NRLS.*[41]

17.50 The report was designed to maximise the work that could be automated and minimise the amount of individual judgement required. This is not a criticism of the work done by the NPSA; they had limited resources and had to do the best they could.

Interpreting data

17.51 The occurrence rates of particular categories of incidents were captured by the NPSA, but interpreting their significance presents a challenge. As Dr Woodward told the Inquiry in relation to the reporting of patient accidents by the Trust:

> *Reporting rates of patient accidents ... show a reduction, this combined with an increased reporting rate overall provides an indication that either the Trust was learning about why* [accidents] *happen and preventing them from happening or the reporting, but not the actual incidence, of patient accident was reducing.*[42]

17.52 Mandatory reporting to the NPSA might reduce this difficulty, but would not eliminate it. Both the NPSA and trusts will have difficulty establishing whether staff are under-reporting incidents. However, a mandatory system would at least enable the NPSA to point out the issue to trusts and encourage them to investigate the extent to which their internal reporting system is effective.

40 NPSA WS(Provisional) – NPSA00000000013, para 3.7
41 Annex 3 to NPSA WS(Provisional) NPSA00000000190
42 NPSA WS(Provisional) – NPSA00000000024, para 3.24

Incidents relating to staff shortages

17.53 One category into which incidents were grouped by the NPSA was "staffing, facilities and environment". This masked the extent to which incidents at the Trust were attributed to staffing issues. In this group, taken as a whole, the Trust was not an outlier.[43]

17.54 At the Inquiry's request, the NPSA carried out an analysis of the reports received by the NRLS of understaffing at the Trust, and a paper was submitted by Dr Woodward.[44] No such analysis had been carried out by the NPSA of its own volition, either as a matter of routine or as a result of the publication of the HCC report into the Trust. The reason given for this was that:

> *... [I]nfrastructure and staffing issues are generally considered primarily as incidents for local consideration and data from one individual trust are unlikely to have application across the wider NHS. They are of significance for the Trust in question who should already be aware of these issues because they are the reporters of the data.*[45]

17.55 The paper identified 940 reports involving staff shortages or staff with inadequate skills or experience, in inpatient areas and the accident and emergency department, during the period 2005–2010. In addition to those set out above, examples include the following:

> *For 18 bedded acute ward only one trained nurse and one untrained on duty ... Most of the night shift I start with lots of outstanding jobs from previous shift ... This staffing level at night shift particularly Ward 2 seriously dangerous and these incident form I have done many times, no action no feedback. I am very unhappy about patient care.*[46]
>
> *During the late shift there was no allocation of staff to the four bedded CDU. Upon transferring a patient from minor injuries to the CDU I found one elderly a very distressed patient shouting for help. Another patient said she had been shouting for hours. When I assisted the patient onto the commode her bed was soaked in urine which had started to dry. None of the patients had nurse call buzzers. None of the patients had been given any food or drink.*[47]
>
> *Yet again the experience and quantity of the trained staff is not adequate to cover the floor safely. There were only 2 trained staff who have experience to do 3 jobs ...*[48]
>
> *Yet again the staffing level on nights was appalling. Only 3 trained staff allocated for the next 4 nights ... repeatedly the staffing is dangerously low ...*[49]

43 NPSA WS(Provisional) – NPSA00000000025, para 3.24
44 SW/14 WS0000045717
45 SW/14 WS0000045717
46 SW/14 WS0000045759
47 SW/14 WS0000045763
48 SW/14 WS0000045813
49 SW/14 WS0000045814

Yet again I have come on shift to find only 3 trained nurses on duty (including myself) on a Saturday night!!!!!! This also happened on Friday night as well ... Unfortunately I am being told that this is being addressed ... but looking at the off duty it appears to [be] *becoming the norm again.*[50]

17.56 Dr Woodward was asked about the approach of the NPSA to these reports, and, in particular, the apparent failure of the Trust to listen to or act upon concerns expressed by staff:

Q. But would your evidence be that the NPSA was not equipped to do anything about these incidents, notwithstanding their volume and their seriousness?

A. I would say that the National Patient Safety Agency was not the appropriate organisation to deal with a local staffing issue. These incidents are being reported within, say, that night or that day. I would expect somebody to listen to that – those staff the next day or within a few – a few days of that. I would not expect that to have to reach a national agency after a few months for – for those issues to have been dealt with. So it's the immediacy, the type of incident that is related to staffing and infrastructure needs immediacy, and it needs local action.

Q. But some of these reports would suggest that such action hadn't taken place.

A. Clearly. But if I'm – if I shift you to the mindset of the National Patient Safety Agency, it's receiving all of these reports and looking at it from a topic base, not an organisational base. I accept that reviews of infrastructure and staffing would be a useful topic base for us to really focus on.

Q. But if we look at the period during which this was happening, what look on occasions to be quite distressed members of staff are reporting distressing incidents saying nothing has been done about it. If we assume for the moment that the trust management was not listening or capable or for whatever reason doing anything about it, who else was?

A. Those types of incidents would not, unless the patient had died, been generally reported as serious untoward incidents. So it's unlikely that the PCT or the SHAs would have been looking at those incidents. So it is highly reliant on a good local risk management system.[51]

17.57 The NPSA was the only organisation external to the Trust that routinely received reports of this nature from the Trust's own reporting system, a state of affairs known to the NPSA. However, the NPSA neither analysed the individual reports, nor shared them with other bodies which monitored performance or patient safety.[52]

50 SW/14 WS0000045814
51 Suzette Woodward T102.48–49
52 Suzette Woodward T102.54–55

17.58 Professor Sir Liam Donaldson suggested to the Inquiry that the analysis of such information should be part of the NPSA's role:

> *If for example, the nurses are routinely raising a lack of staffing, this is not an incident or a near miss, but it is a pre-emptive concern about environmental factors that could lead to incidents occurring. It should also be recognised that reporting has historically focused on post-event reports rather than pre-emptive concerns. This is one of the things the NRLS has been set up to try and address; it looks at factors that may provoke errors or lead to harm ... This sort of "soft" intelligence is, in my experience, the really telling data as to what cultures are like, and is an early indicator of even greater problems. However, there are methodological issues of how to deal with such soft intelligence, as you have to look at the resources and cost available, and when to draw the line between over-analysing the minor incidents to the detriment of potentially major problems.*[53]

17.59 A patient safety incident is defined as:

> *Any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care.*[54]

17.60 This places a focus on "incidents" rather than "risks". Thus, looking at some of the examples given above, the "incident" could be defined as a failure to attend to a patient, brought about by a staff shortage. Alternatively, it might be possible to define the "incident" as being the staff shortage itself. Sir Liam regarded staffing issues to be an example of a risk rather than an incident. Dr Woodward, in the passage cited above, seemed to have regarded the occurrence of staff shortages as capable of being an incident, but one which could in practice only be dealt with at a local level. It may be that this apparent ambiguity contributed to there being no analysis by the NPSA of this theme.

17.61 Sir Liam stressed that if the remit of the NPSA was to be extended beyond incidents of actual harm and near-misses, to encompass "risks and hazards" such as low staffing levels, the following points would require consideration:

> *First, if reporting were to be widened to risks and hazards (and it is a legitimate point of view that it should) this would need to be a conscious policy decision. It would open up reporting to millions of further incidents ... Second, in my opinion the responsibility to correct or make safe a risk or hazard is a local matter in the care environment. It should be addressed, and resolved, locally, unless it reflects a widespread problem across the NHS.*[55]

53 Donaldson WS(1) WS0000070155–56, para 156
54 NPSA0004000009, *Seven Steps to Patient Safety for Primary Care: the full reference guide* (May 2006), NPSA, p9
55 Donaldson WS(1) WS0000070157–58, para 161

17.62 The analysis detailed above shows what could have been done with the information the NPSA received. The information of this type received by the NRLS is a resource from which analysis of the type undertaken for the Inquiry could be performed routinely or as a risk-based assessment. Clearly, not every detail in every trust can receive this sort of attention routinely without an IT system which is highly expensive, and no doubt prone to the problems all such systems appear to suffer in development. However, it is important that thought is given to devising methods to extract the maximum benefit from the effort put into the collection of the data. Serious consideration should be given to the potential of the system for producing analyses of the relationship between safety incidents and staffing shortages and how it can be exploited. It would be impractical to suggest that the sort of exercise rehearsed above could be done for every trust in the country on a regular basis and, therefore, a risk-based approach would be required.

Incidents in the accident and emergency department

17.63 The Trust began reporting incidents to the NRLS in June 2005. In order to analyse the reporting patterns of NHS organisations and to prepare feedback reports, the NPSA would compare similar organisations in "clusters", determined by size and care setting, though not geography. The Trust was within the "small acute trusts" cluster.[56]

17.64 The Trust's A&E department was, initially, slow to report incidents to the NRLS. Between April 2006 and March 2007, no reports whatsoever were submitted. From April to September 2007, reports from A&E represented just 1.8% of those submitted by the Trust, as against an average of 5.5% across the relevant cluster. This rose to 2.5% in the period October 2007 to March 2008, before jumping sharply to 6.6% in April–September 2008, during the period of the HCC investigation into the Trust.[57] These figures no doubt reflect attempts to improve the governance and learning culture of the department, much criticised by the HCC in its letter of 23 May 2008.[58]

17.65 The low rate of reporting in 2006–2008 may have indicated that the A&E department did not have a learning culture, which might in turn have been the result of attitudes to patient safety presenting an increased risk of patient harm. However, the high-level analysis supplied by the NPSA as to the rate of reporting could not reliably indicate whether this was the case, or whether the subsequent increase in reporting demonstrated that the department was becoming more or less safe for patients over the period. This could only have been detected by local scrutiny of the department by the Trust itself, or by a local commissioning, regulatory or supervisory body.

56 NPSA WS(Provisional) – NPSA00000000019, para 3.17
57 NPSA WS(Provisional) – NPSA00000000027, para 3.25
58 HCC0004000331–34, Letter from Dr Heather Wood, HCC Investigations Manager, to Martin Yeates (23 May 2008)

Mortality

17.66 The NPSA does not receive information about mortality rates and was unaware of the Hospital Standardised Mortality Ratio (HSMR) reports produced by Dr Foster. Its systems could not produce analyses comparable to HSMR.[59]

17.67 While this is understandable, the NPSA clearly does receive incident reports involving deaths in hospital and consideration should be given as to whether there is any way in which information from those reports could enhance consideration of the significance of the HSMR.

Cause for concern letters

17.68 The process of sending cause for concern letters to trusts (described in general above) is intended to cover only incidents of exceptional seriousness. Less than 1% of incidents resulting in severe harm or death precipitate the sending of a letter.[60] Between November 2008 and June 2010, the NPSA sent six cause for concern letters to the Trust. Only 10%–20% of trusts received such letters, so in this respect the Trust was marked out from its peers.[61] However, amongst those trusts that did receive letters, the Trust was not exceptional. Over a similar period, 29 trusts received five or more letters, and of those that did, 20 received more than Mid Staffordshire, and five trusts received twice as many.[62]

17.69 Dr Woodward told the Inquiry that, as with all NPSA data, the numbers of cause for concern letters received by a trust could be affected by the completeness and detail of its reporting. Trusts which did not upload all of their death and severe harm events, or who gave only minimal descriptions of the incidents, would be less likely to receive letters than those that reported, with full clinical detail, each serious incident that occurred there.[63]

17.70 The first letter sent to the Trust, on 6 November 2008, referred to the following report submitted to the NRLS:

> *Patient admitted unwell with septic shock ... He was referred to critical care out reach on admission but I was told that they were too understaffed to see him and that they only look after surgical patients. He was then referred to CCU for level 2 care on several occasions but not accepted as it was felt he did not require admission and then due to a lack of nursing staff on CCU. He was too unwell to manage on EAU and the nursing staffs were unable to devote the time necessary to look after him properly ... In addition he was prescribed 2 units of blood and IV fluids to be given fairly rapidly but they did not go*

59 Suzette Woodward WS0000045005, para 127
60 Suzette Woodward WS0000045007–08, para 134
61 Suzette Woodward T102.62
62 Suzette Woodward WS0000045008, para 135
63 Suzette Woodward WS0000045008, para 136

through on time again due to nursing levels on EAU being too low to look after him properly. This man ultimately survived his sepsis but his chances of survival were severely diminished by the quality of care he received.[64]

17.71 The letter requested a copy of the Trust's investigation into the incident and a note of any actions taken to prevent recurrence. The NPSA received a substantive response from the Trust Head of Governance, Trudi-Anne Williams, on 5 December 2008. It read:

Further enquiries have revealed that this incident was not formally investigated in the depth that it clearly warranted. This has now been rectified, and an anonymised version of the investigation is attached.[65]

17.72 The investigation was carried out by a consultant in critical care and anaesthesia, and recommended a six-point proposed action plan. Ms Williams undertook to address the issues raised with the executive team.[66]

17.73 Two further letters of concern were sent during the period of the Inquiry terms of reference. The first, dated 23 December 2008, concerned a delay in the administration of thrombolytic (anti-clotting) medication to a patient following a heart attack. On 23 January 2009, the Trust responded with details of the investigation that had been undertaken in response. The second incident, which caused a letter to be sent on 25 February 2009, concerned a delayed cancer diagnosis resulting from a failure of investigation persisting over a period of eight years. The NPSA were notified by the Trust of an independent investigation into the incident in March 2009, and were provided with a report by the Trust's Head of Governance on 14 October 2009.[67]

17.74 Dr Woodward told the Inquiry that the Trust's response to the cause for concern letters had been "of a generally reasonable overall standard". Although in one instance the NPSA had to send a reminder following a letter, the Trust had otherwise acknowledged receipt in a timely manner and provided incident reports within a reasonable time. It seemed to Dr Woodward that the incidents had been reviewed by appropriate specialists and "all of the concerns raised by the ... letters were answered by the Trust's responses".[68]

17.75 Despite the fact that the cause for concern letters by definition highlight only incidents of exceptional seriousness, resulting in serious harm to patients or death, the NPSA have never

64 SW/24 WS0000046227
65 SW/24 WS0000046229
66 SW/24 WS0000046230, WS0000046233
67 NPSA WS(Provisional) – NPSA00000000042–43, para 3.56
68 Suzette Woodward WS0000045008, para 136

copied letters to the Healthcare Commission (HCC) or the CQC, or to any other NHS agency such as the relevant SHA or PCT. Dr Woodward told the Inquiry that:

> *The NPSA had to take responses by the Trust at face value. If* [the] *NPSA had copied the HCC/CQC into the correspondence, it would have linked the NPSA to the regulators on an ongoing basis in the eyes of the NHS organisations, which … was undesirable.*[69]

17.76 However, Dr Woodward accepted that in light of the maturing patient safety culture within the NHS, "it could be appropriate" to share information with bodies such as the CQC on incidents sufficiently serious to provoke cause for concern letters, and that "consideration definitely could be given" to the NPSA adopting such a course.[70]

17.77 Where information on serious incidents comes to light, which might be indicative of systemic failures, it is desirable that it is shared with the regulators. It is the very fact that the NPSA is not itself a regulator and has no powers to enforce remedial action to protect patients that should require it to hand information to those who can. A cause for concern letter in itself suggests that the matter requires escalation. If that is truly the case, the logic of that assessment requires action as opposed to a continued exchange of correspondence.

17.78 In fact, the NPSA did contact the CQC over concerns about the Trust, having detected a pattern of incidents between April and May 2009, a time of heightened alert following the publication of the HCC report. Sixteen incident reports of severe harm to patients had been submitted to the NPSA, involving a variety of patient safety issues. The reports suggested that there may have been a problem with the safety of routine clinical care processes in a range of clinical areas across the Trust. In addition, there had been three deaths reported via the SHA's STEIS, which reported on SUIs, two of which could not be found on the NRLS. As a result, in May 2009, the NPSA Chief Executive spoke to the Trust Chief Executive (then Eric Morton), to alert him to the NPSA's concerns and inform him that the NPSA would be contacting the CQC. The NPSA Chief Executive duly did so in an email to the CQC on 18 May 2009. In June 2009, the Trust Head of Governance sent the NPSA a report into all 16 incidents, detailing actions taken by the Trust in response.[71]

17.79 Dr Woodward told the Inquiry that the NPSA had never before, or since, contacted the quality regulator directly, and that this was a "complete one-off" resulting directly from the "heightened awareness" of problems at the Trust following the publication of the HCC report.[72]

69 Suzette Woodward WS0000045009, para 138
70 Suzette Woodward T102.68–69
71 NPSA WS(Provisional) – NPSA00000000044–45, para 3.60
72 Suzette Woodward T102.18–19

17.80 This contact was exceptional, but demonstrates that the NPSA could have made a greater contribution to patient safety if its systems had been developed. Doubtless, this requires more resources than those with which they had been provided.

Absence of analysis capable of exposing serious concerns

17.81 Dr Woodward was asked why, given the quantity of information in its possession on patient safety incidents at the Trust, the NPSA did not share the concerns that led the HCC to launch its investigation into the Trust in March 2008:

> *The NPSA did not have any concerns over and above some individual incidents which led the NPSA to write to the Trust ... The NPSA does not review its data in the same way as an inspecting, performance managing or regulatory organisation would. The prime purpose of the NPSA is to promote national learning and consequential improvements in patient safety ...*
>
> *Local learning is the responsibility of local trusts. If there are concerns about individual trusts the NPSA would expect these to be addressed by the SHA and PCT (as performance managing organisations) and/or (depending upon the seriousness or severity) the regulators such as the HCC.*[73]

17.82 This demonstrates the limits of the NPSA's function. It might have been better to name the organisation the National Patient Safety Information Agency. There is nothing wrong with so limiting its role, provided that its jurisdiction is well understood, and that the information it gathers is made available to those who are in a position to take effective action to protect patients. While first on such a list must be acute trusts themselves, the organisations who need to know the information also include the performance managers, regulators and the commissioners. Such closer cooperation would have required a facility where the NPSA could have been requested to analyse its data for a particular purpose, or to facilitate others in that task.

Narrative of Memorandum of Understanding with the Care Quality Commission

17.83 In April 2010, the NPSA and the CQC signed a data-sharing agreement, prior to which the CQC had access only to the summary reports made available to the general public.[74] From April 2010 onwards, the CQC has requested and been given access to all moderate or severe incidents and deaths reported to the NPSA, amounting to around 10,000 cases per week.[75] These notifications result in an immediate alert being sent to the relevant inspector.[76] The CQC is also provided with full individual organisation reports, which are not available to the general public. Richard Hamblin, Director of Intelligence at the CQC, told the Inquiry that despite an

73 Suzette Woodward WS0000045015–16, paras 153–154
74 SW/33 WS0000046440; Suzette Woodward WS0000045016, para 156
75 Suzette Woodward WS0000045016, para 156
76 Hamblin WS0000031050, para 172

initial period of "reluctance" from the NPSA, motivated by concerns that sharing information with a regulator might discourage reporting, the system was now "well established".[77] However, Dr Woodward had not identified a significant impact on reporting as a result of this shared data.[78]

Patient safety managers

17.84 Prior to 1 April 2008, the NPSA employed local patient safety managers who helped trusts develop their local risk-management systems and offered training in the root cause analysis of patient safety incidents.[79] The managers' remit did not include scrutinising the content of a trust's patient safety incident reports; face-to-face contact with each trust was limited to between three and five days per year, and there would be no contact with clinical staff. The focus was not on investigating problems within an organisation, but instead on helping those organisations to analyse their own data.[80]

17.85 The patient safety managers were transferred to the patient safety action teams, under the aegis of the SHAs, on 1 April 2008. This came about as a result of a recommendation in the *Safety First* report published in December 2005, more than two years previously. Dr Woodward told the Inquiry that employment issues accounted for the time taken to achieve this, in particular whether the managers would be employed by the NPSA or the SHAs.[81] The re-organisation of the SHAs also took place during this period.

17.86 Patient safety managers were a limited resource, which appear to have done little more than assist trusts with systems. They did not have contact with clinical staff. They made no records of their meetings. Therefore, they are unlikely to have made a significant contribution to patient safety except through helping improve local reporting systems.

77 Hamblin WS0000031050–051, para 173
78 Suzette Woodward WS0000045016, para 156
79 Suzette Woodward WS0000044989, para 75
80 Suzette Woodward WS0000045000–01, para 113
81 Suzette Woodward WS000004489–90, paras 75–79

Patient safety alerts

What they are

17.87 Dr Woodward explained that patient safety alerts were solutions drawn up to address medical problems, which had been repeatedly encountered and resulted in serious harm and deaths.[82] The process of producing these alerts would be a six-step process:

> *i. The first step is for a team to review all the serious incidents (severe harm and incidents which lead to death as mentioned above) to identify themes from surgical incidents, medication incidents, paediatric incidents and so on.*
>
> *ii. The second step is to discuss the incidents at a weekly meeting to identify whether there are any high risk issues arising out of these themes which require more depth analysis.*
>
> *iii. The third step is to then use examples of the data to drill down further across all other levels of harm.*
>
> *iv. The fourth step is to consider whether national guidance is required to alert the NHS to the risk.*
>
> *v. The fifth step is to create guidance and work up any recommendations or solutions to address the risk.*
>
> *vi. The sixth step is to issue the guidance in a number of different forms; low but important risks are disseminated through a newsletter 'Signals', urgent risks are disseminated with simple recommendations are disseminated through a Rapid Response Report and urgent risks with more complex recommendations and worked up solutions are disseminated through Patient Safety Alerts.*[83]

17.88 Rapid response reports and patient safety alerts would be issued to the NHS via what is now called the Central Alert System (CAS), previously known as the Safety Alert Broadcast System (SABS), and would be directed to a particular audience. This audience could range from being all acute trusts or all mental health trusts, or could be directed as narrowly as only to, for example, orthopaedic departments.[84]

17.89 All alerts would contain a deadline, by which the measure necessary to deal with the problem identified had to be implemented. The CAS/SAB systems would require trusts in receipt of alerts to notify the NPSA of the extent to which they had been implemented. There would be a range of six possible responses on receiving an alert, ranging from acknowledgement to completion. If a trust is unable to complete all the actions detailed in the alert, the NPSA

82 Suzette Woodward T102.78–9
83 Suzette Woodward WS0000044974, para 28
84 Suzette Woodward WS0000044975, para 29

considers it acceptable for the trust to put the remaining issues on the trust risk register, as long as there is an action plan with clear deadlines for achieving compliance.[85]

Trust's compliance with alerts

17.90 Dr Woodward pointed out that compliance with patient safety alerts needs improving across the NHS and that, as at June 2010, there were 31 trusts who had not implemented 10 or more alerts within the expected deadline.[86] The Trust's level of compliance with alerts was as follows:[87]

Table 17.1: Mid Staffordshire's level of compliance with alerts

Period	Total	Total completed	Total completed before deadline	% completed before deadline	% completed after deadline
1 April 2004 to 31 March 2008	367	365	245	67%	33%
1 April 2008 to 31 March 209	118	117	90	76%	24%
1 April 2009 to 20 July 2010	148	131	58	39%	49%

17.91 The Trust therefore managed implementation of alerts by the deadline in 67% of cases between April 2004 and March 2008, 76% in the period April 2008 to March 2009, and 39% in the period between 1 April 2009 and 20 July 2010.

17.92 Between 1 January 2005 and 31 December 2009, the Trust's overall compliance with alerts issued by the NPSA and the DH by the set deadline was 71%. This level of compliance by the required deadline compares to a level of 72% amongst other comparable small acute trusts. The Trust's rate of implementation for 'NPSA-only' alerts was 49% as compared to 50% amongst similar sized peers.[88] Therefore, the rate of compliance by the Trust with patient safety alerts in the relevant period was only slightly below the average for its peers.

Responsibility for follow up

17.93 The Inquiry was told by Dr Woodward that the NPSA did not follow up the failure of individual trusts to implement safety alerts, considering this to be the role of the SHAs, the PCTs and the CQC.[89] Dr Woodward's evidence was not consistent with that given by Peter Blythin, Director of

85 Suzette Woodward WS00000440976, paras 31–8
86 NPSA WS(Provisional) – NPSA00000000031, para 3.33
87 NPSA WS(Provisional) – NPSA00000000031, para 3.33 table 10
88 Suzette Woodward WS0000045010, para 139
89 NPSA WS(Provisional) – NPSA00000000031, para 3.34

Nursing at the West Midlands SHA (WMSHA), who told the Inquiry that historically the WMSHA had not received patient safety alerts and did not monitor trust compliance with them.[90] Nor was it consistent with the evidence of Amanda Sherlock, Director of Operations at CQC.

17.94 Dr Woodward was referred to the following passage of Ms Sherlock's evidence to the Inquiry:

> *We have no power to enforce the implementation. So we would not as a matter of course follow up that every patient safety alert had been implemented in an organisation. If, however, we were alerted to the non-implementation and there was a subsequent serious incident that could have been avoided by the implementation of an alert, we would follow that through with the organisation to identify whether there had been a failing in compliance against our essential standards.*[91]

17.95 Dr Woodward's response was as follows:

> *A. My assumption has always been that the regulator would follow up on compliance against alerts.*
>
> *Q. It sounds as though the evidence I've just read to you would come as something of a surprise, then?*
>
> *A. Yes.*
>
> *Q. How did you envisage that they would follow up the alerts?*
>
> *A. I'm not entirely sure what processes they would use. It was an assumption that alerts would be followed up through their annual process.*
>
> *Q. Well, to your knowledge, was there a standard that specifically referred to them or you weren't familiar with that amount of detail?*
>
> *A. As I recall – as I recall, and I may have this wrong, the core standards that I referred to as core standards, the original standards, talked about compliance with the NPSA guidance.*[92]

17.96 This appears to indicate a lack of engagement with the issue of how the work of other agencies might complement that of the NSPA. Even though it is not a regulator, the NPSA, together with national and regional oversight bodies and the regulators, had a responsibility for ensuring clarity about how the failure of NHS organisations to engage with this important safety system was followed up. This is an example of the confusion that can arise from the large number of organisations in the healthcare system having potentially overlapping

90 Blythin T69.156–157
91 Sherlock T85.84
92 Suzette Woodward T102.88–89

functions, and being subject to multiple sources of guidance. The result is potentially a lack of action in addressing significant patient safety concerns.

Information received from the public

17.97 The NPSA had an inquiry helpline and also, from time to time, received emails from the public. Only one email which was unearthed dated 17 May 2004, was of potential interest to the Inquiry, from a senior staff nurse who may have been working at the Trust:

> *Hi,*
>
> *I am a very concerned senior staff nurse working for the NHS in Staffordshire. I moved from a trust in Scotland where staffing levels I felt only occasionally compromised patient safety and care. However, now I am constantly worrying about these same issues due to chronic staff problems which I feel could be much better managed if proper risk assessments and different priorities were looked at ...*
>
> *I work on a medical ward with 28 beds and most of the patients are elderly and dependant. A typical staff ratio is 14 patients to 1 trained nurse ... I am constantly submitting incident report forms but nothing seems to change and I never receive feedback.*
>
> *I would welcome your advice on the way forward.*[93]

17.98 There is no record of what, if anything, was done in response; the likelihood is nothing.

17.99 Dr Woodward told the Inquiry:

> *Q. But the NPSA would not itself have either openly or behind the scenes have copied this to any external body ... or regulator?*
>
> *A. No.*
>
> *Q. Why was that?*
>
> *A. It wasn't normal practice at the time.*
>
> *Q ...* [W]*hy wasn't it normal practice in the event of receiving what looks almost like a whistleblowing email?*
>
> *A. That's a good question. I think that the mindset would have been to refer the person back to the people who could have dealt with it in a much more immediate way than a national agency talking to another national agency.*

93 SW/13 WS0000045715

Q. Given the title of the NPSA ... did the NPSA anticipate that it might attract, however misguided they might be, whistleblowers?

A. Yes, which is why we had a standard response to people that did try to get in touch with us, which was to refer them to the more appropriate people to address that.

Q. But would you have referred a person such as this to an organisation such as Action Against Medical Accidents or to the terms, for example, of the Public Interest Disclosure Act of 1998?

A. That wasn't in the template. Neither of those were in the template. So the template would have ... considered the ones I've mentioned earlier.[94]

17.100 The NPSA may not be a regulator, but as a safety agency it had a responsibility to ensure that information which may have revealed concerns about patient safety be referred to organisations in a position to take action. In the case of this email, which might in theory have referred to any trust in Staffordshire, it should have been copied to the healthcare systems regulators as well as the SHA.

Patient Environment Action Teams

17.101 The NPSA also oversaw an inspection system called the Patient Environment Action Team (PEAT). The system involved self-assessments being conducted by a local team from a trust, with representatives chosen by that trust.[95] From April 2013 the PEAT programme will be replaced with a Patient Led Inspection programme.[96]

17.102 The programme is an annual assessment of inpatient healthcare sites in England and is overseen by the DH. The process was supported and managed by the NPSA, and results were analysed by the NHS Information Centre and the results posted on the NPSA website. Its purpose was a self-assessment of non-clinical aspects of patient care including looking at standards of patient environment and food. From 2009, an additional assessment relating to standards of patient privacy and dignity was added.[97]

17.103 From 2004, grades for NHS organisations were set as "poor", "acceptable", "good" and "excellent". Each trust would receive guidance on the assessment via the NPSA website and detailed training was provided when the programme was established in 2000 and continued to be provided to update assessors on changes to the process. The data would be used for trusts themselves to monitor their environments; by regulators to rate trusts and assess their

94 Suzette Woodward T102.58–59
95 NPSA WS(Provisional) – NPSA00000000034, para 3.37
96 http://mediacentre.dh.gov.uk/2012/01/06/pm-announces-new-focus-on-quality-and-nursing-care/
97 NPSA WS(Provisional) – NPSA00000000034, para 3.38

compliance with related standards; and for SHAs to manage the performance of those organisations failing to achieve the required standards.[98]

17.104 In relation to the PEAT inspections of the Trust, between 2006 and 2010 the assessments were carried out by teams largely made up of senior Trust staff, usually including the Housekeeping Manager and Catering Manager, as well as a representative from the hospital user group.[99] From 2005 to 2009, with the exception of being rated as "acceptable" for its environment in 2008, the Trust was rated as "good" or "excellent" for its environment and food.[100]

17.105 Dr Woodward argued that the PEAT assessments did not encounter problems with objectivity and that findings were consistent with the HCC and the CQC cleanliness ratings based on inpatient surveys.[101] However, teams consisting of trust staff focusing on issues of hygiene, cleanliness and patient dignity will improve the culture within an organisation if they are well run, apply objective and rigorous standards and report their findings in an open and informative manner. They do lack an independent element, which it would be desirable to import. While it may have been impracticable for the NPSA to have its own team of inspectors for this purpose, it should be possible to organise for mutual peer-review inspections, or the inclusion of representatives from outside the organisation in PEAT teams. Consideration could also be given to involvement from time to time of a representative of the CQC.

The National Patient Safety Agency relationship with other organisations

Strategic health authorities

17.106 Initially the NPSA's attitude was that it was a national organisation set up to assist with national learning and to encourage openness and transparency in patient safety culture. The SHAs were viewed as performance managers and there were concerns expressed by users of the NPSA that if the NPSA shared information on incident reporting with local SHAs it would result in undesirable performance management consequences. Therefore, initially the NPSA did not voluntarily share information with the SHAs and would instead refer them to the acute trusts directly.[102] The SHAs would therefore have access to the same raw data as the NPSA but would not have the benefit of the NPSA's comparative analysis of trust reporting patterns.

98 NPSA WS(Provisional) – NPSA00000000034, para 3.39–40
99 NPSA WS(Provisional) – NPSA00000000036, table 11
100 NPSA WS(Provisional) – NPSA00000000037, table 12
101 Suzette Woodward WS0000045003, para 118 and 123
102 Suzette Woodward WS0000045012, para 141

17.107 From 2007 onwards, the NPSA changed its approach, having felt that the culture of patient safety in the NHS as a whole was maturing. As a result the NPSA began to share an increasing amount of information with the SHAs.[103]

Monitor

17.108 The NPSA did not regularly share information with Monitor. For the reasons given, any subsequent organisation exercising its functions should find ways of doing so.

The Healthcare Commission and the Care Quality Commisssion

17.109 Following the publication of the *Safety First* document in 2006, the NPSA began to share data more widely.[104] In July 2008, as part of the HCC's investigation into the Trust, the NPSA was asked to conduct an ad hoc review of patterns of reporting to the NRLS from the Trust in light of an excess in mortality for patients admitted for jejunum surgery in April 2007. The report entitled *Reporting from Mid Staffordshire NHS Trust (small acute trust)* was sent to the HCC investigations team on 21 July 2008.[105] No specific concerns around jejunal surgery were identified and no further information was sought by the HCC.[106]

17.110 On their own initiative the NPSA reviewers also looked for more general issues of patient safety within the Trust and suggested to the HCC that the following would benefit from further exploration:

i. Indications of a weak reporting and learning culture;

ii. A recent increase in reports of staffing shortages;

iii. Indications of problems with equipment for morbidly obese patients;

iv. Capacity to provide pre-operative care.[107]

17.111 In relation to safety alerts, Dr Woodward described how the HCC would choose which alerts each year to follow up on. Although the NPSA would work to develop relevant inspection guides, the delivery of inspections and following up with organisations identified as not complying fully with alerts would be led by the HCC and would not directly involve the NPSA. In this way ensuring compliance remained the responsibility of the HCC and did include further input from the NPSA.[108]

103 Suzette Woodward WS0000045012, para 143
104 Suzette Woodward WS0000045013, para 146
105 NPSA WS(Provisional) – NPSA00000000044, para 3.58
106 Suzette Woodward WS0000045013, para 147
107 Suzette Woodward WS0000045014, para 148
108 Suzette Woodward WS0000045014, para 150

Conclusion on the exchange of information

17.112 The reluctance to be seen as a part of the performance management or regulatory system was understandable, but NHS culture should have matured to a stage where open reporting and willingness to learn is a sufficient motivation to report incidents in the knowledge that the information will be used throughout the system.

17.113 Openness requires acute trusts to demonstrate that not only are they reporting incidents, but that they are implementing learning from them. The more they do so for themselves, the less the need for external intervention. Prudent organisations will enhance their reputations by their active participation.

17.114 The CQC should be able to exploit the potential of the safety information obtained by the NPSA to assist it in identifying areas for focusing its attention. There needs to be a better dialogue between the two organisations (the CQC and, now, the NHS Commissioning Board) as to how they can assist each other.

17.115 Therefore, sharing of information with performance managers and regulators should be seen as a necessary part of the role of collecting safety information. One important qualification is that the functions of the NPSA should be concerned only with safety and it should not allow itself to be drawn into the wider field of performance statistics.

Conclusions

17.116 Patient safety information, in the form of incident reports, is a vital part of what is required for patient protection. Without it, no safety system can begin to be effective. The development of a system for collecting such information nationally and providing learning from it has to be welcomed. The NPSA sought to master a challenging field and has made considerable progress. However, the experience of Stafford has shown that the existing system played no part in the uncovering of the lack of safety there. Therefore, there is more that could be done.

Implementation of the National Reporting and Learning System

17.117 It is clear that a very positive development for patient safety has taken a long time to implement, and that further development is still required. This is in part due to the complexities of organising a national system, but also in part due to the challenges thrown up by the many structural re-organisations of the NHS during the relevant period, and the relatively low priority accorded to this area of activity as a result.

Reporting requirements

17.118 The system is now sufficiently sophisticated and developed that reporting to the NPSA of all adverse incidents should be mandatory on the part of trusts. In a culture of openness and

learning a well-run trust should welcome the opportunity to contribute to a national resource. In any event with available electronic systems it need not result in additional expense over and above what is required.

17.119 What is more important is that the output of the system is anonymised. This is a learning system, not one of accountability.

Individual reporting

17.120 The system should be developed to make more information available from this source. Such reports are likely to be more informative than the corporate version, where an incident has been properly reported, and invaluable where it has not been.

17.121 Individual reports of serious incidents which have not been otherwise reported should be shared with a regulator for investigation, as the receipt of such a report may be evidence that the mandatory system has not been complied with.

The future

17.122 The NPSA was abolished as an independent entity on 1 June 2012, and its functions have been transferred to the NHS Commissioning Board. The National Reporting and Learning System is to be continued under its auspices.[109]

17.123 Safety is such a crucial aspect of protecting patients, it is questionable whether it should be controlled by a body under pressure to ensure the delivery of economic and financial objectives as well as quality ones. Wherever the function resides, its resources need to be well protected and defined.

17.124 Consideration should be given to the transfer of this valuable function to a semi-independent arm of the systems regulator. Since the inception of the NPSA, there has been a huge shift in the approach to the reporting and analysis of errors and near misses. The responsibility to report and learn is now much more clearly a responsibility of professional clinical life, and the consequences of not doing so are set out in professional codes of conduct. Whereas when the NPSA was created, it would have been unacceptable for a voluntary reporting system to be used for anything else but learning, there is now a wider acceptance of the use of such data for investigation and benchmarking. Because of this, the inclusion of the reporting activity within a quality surveillance system or regulator is much more acceptable.

109 www.npsa.nhs.uk/corporate/news/transfer-of-patient-safety-function/

Summary of recommendations

Recommendation 97

The National Patient Safety Agency's resources need to be well protected and defined. Consideration should be given to the transfer of this valuable function to a systems regulator.

Recommendation 98

Reporting to the National Reporting and Learning System of all significant adverse incidents not amounting to serious untoward incidents but involving harm to patients should be mandatory on the part of trusts.

Recommendation 99

The reporting system should be developed to make more information available from this source. Such reports are likely to be more informative than the corporate version where an incident has been properly reported, and invaluable where it has not been.

Recommendation 100

Individual reports of serious incidents which have not been otherwise reported should be shared with a regulator for investigation, as the receipt of such a report may be evidence that the mandatory system has not been complied with.

Recommendation 101

While it may be impracticable for the National Patient Safety Agency or its successor to have its own team of inspectors, it should be possible to organise for mutual peer review inspections or the inclusion in Patient Environment Action Team representatives from outside the organisation. Consideration could also be given to involvement from time to time of a representative of the Care Quality Commission.

Recommendation 102

Data held by the National Patient Safety Agency or its successor should be open to analysis for a particular purpose, or others facilitated in that task.

Recommendation 103

The National Patient Safety Agency or its successor should regularly share information with Monitor.

Recommendation 104

The Care Quality Commission should be enabled to exploit the potential of the safety information obtained by the National Patient Safety Agency or its successor to assist it in identifying areas for focusing its attention. There needs to be a better dialogue between the two organisations as to how they can assist each other.

Recommendation 105

Consideration should be given to whether information from incident reports involving deaths in hospital could enhance consideration of the hospital standardised mortality ratio.

Chapter 18
Medical training

Key themes

- The quality assurance and management documentation seen by the Inquiry did not demonstrate an adequate recognition of the role medical education and training activity can play in safeguarding patients or of the importance of training taking place in environments not complying with minimum safety and quality standards.
- Since the events at Stafford the General Medical Council (GMC) has taken encouraging steps to increase the focus on patient safety, including a specific question in its trainee survey, the creation of a response to concerns process and an audit of emergency department rotas.
- The GMC has a justifiable concern in relation to the safety of patients that European Economic Area (EEA) practitioners do not have to demonstrate proficiency in English. There appears to be no reason why such a requirement could not be imposed on all candidates for registration.
- The GMC's assessment of Approved Practice Settings relied on the results of the Healthcare Commission's (HCC's) Annual Health Check ratings.
- The GMC's reaction to the HCC report on the Trust did not reflect the gravity of its findings. They may have been inhibited by the limited interventions available to them.
- Training oversight is likely to have been diverted by the difficulties surrounding the failed introduction of the medical training application process (MTAS).
- The Keele University Medical School's system of oversight at the relevant time did not have a sufficient focus on patient safety and care standards issues.
- Surveys of the type administered by the Postgraduate Medical Education and Training Board (PMETB) suffered from a number of disadvantages resulting in it being less likely that concerns would be exposed, and they need development to exploit the information about standards of service likely to be known to trainers and trainees.
- Self-assessments provided by the Trust to the Deanery failed to disclose the true state of affairs.
- The system for reporting Deanery visits to the Trust did not give sufficient weight to concerns raised by trainees with regard to their relevance to patient safety.
- The Deanery organised a degree of rigorous supervision in response to Dr Turner's complaints about the Trust's Accident and Emergency (A&E) but the Dean took no personal steps to liaise about these with the HCC after becoming aware of its investigation.

Introduction

18.1 The Inquiry has received a considerable amount of evidence about medical education and training (as distinct from nurse training) but it is not within the Inquiry's remit to review the subject generally. Its relevance is to examine the relationship between the education and training system and the systems intended to ensure the delivery of fundamental patient safety and quality standards.

18.2 There are a number of themes that require examination:

- The need for practical training to take place in environments which provide services compliant with fundamental standards and to avoid compromising students' and trainees' professional experience and status;
- The contribution to the protection of patients of the systems monitoring training;
- The contribution of trainees to the protection of patients and exposure of deficiencies;
- The protection of trainees from deficient training environments.

18.3 This chapter will give an overview of the system for education and training during the period under review, the experience of training at Stafford, and the lessons to be learned from that experience. The issue of academic education has not been addressed by the Inquiry.

Medical education and training overview

Delivery of education and training

18.4 The typical course followed by a medical student is as follows:

- Undergraduate medical study at a university medical school during which students will attend clinical placements in hospital and community settings.[1] In the case of the Trust the location for placements is at the Keele University Medical School.
- The foundation programme which is the two-year postgraduate training course that is compulsory for all medical graduates. This replaces the former system of pre-registration house officers and senior house officers. During each year, students would typically undertake three four-month placements. The foundation programme is delivered by foundation schools which bring together a number of organisations working in collaboration, such as trusts, medical schools and the deanery. In the West Midlands there are five linked but individual schools.[2] In each placement each individual trainee will have a clinical supervisor, and will also have an educational supervisor.
- Specialty training programmes which last for several years and in which training in a chosen specialty is given. Successful completion leads to a Certificate of Completion of Training (CCT), and entitlement to entry on the General Medical Council (GMC) specialist or

1 Hughes WS0000062159, para 7
2 Hughes WS0000052160, para 9

GP register. The programmes are delivered through postgraduate specialty schools. There are 11 such schools in the West Midlands which oversee the delivery of educational outcomes through individual local education providers (LEPs). LEPs can be trusts, specialist trusts, primary care trusts (PCTs), mental health trusts and other specialist centres. Each LEP has a learning and development agreement with the postgraduate deanery.

National training regulators

Before 2005

18.5 Before 2005 responsibility for medical education and training was shared between the GMC and the 17 Royal Colleges:

- The GMC had responsibility for undergraduate medical education.
- The Royal Colleges had responsibility for postgraduate specialty training.
- The regulator was the Specialist Training Authority (STA) of the Royal Colleges, and as agents of the STA, the colleges were responsible for accreditation and quality assurance of the training. The individual colleges undertook visits to apply the formats and standards approved by the STA.
- Quality assurance visits by specialist advisory committees responsible to the STA via the appropriate college took place at least every five years.

2005 to 2010

18.6 Following the report of the Bristol Inquiry, which found that there were deficiencies in postgraduate medical training and that it was not in the public interest to leave this to the Royal Colleges,[3] the STA was merged with the Joint Committee for Postgraduate Training for General Practice to form the Postgraduate Medical Education and Training Board (PMETB). PMETB assumed its statutory responsibilities on 30 September 2005.

18.7 In summary, from 2005:

- The GMC[4] was responsible for undergraduate training and Foundation Year 1 (FY1). Overriding any statutory duties it might have was an objective of protecting the health and safety of the public:

 The main objective of the General Council in exercising their functions is to protect, promote and maintain the health and safety of the public.[5]

3 Rubin PS/15 GMC00110000004
4 Under the Medical Act 1983 the GMC has the statutory duty, among others, of: promoting high standards of medical education and coordinating all stages of medical education, Section 5(1); ND/2 WS0000048891
5 Medical Act 1983, section 1(1A) inserted (17 December 2002) by The Medical Act 1983 (Amendment) Order 2002 (S.I. 2002/3135), Part 2, Art 3, ND/2 WS0000048889

18.8 During the period from October 2005 to April 2010 the GMC was responsible for:

- Setting the standards of proficiency for primary medical qualifications;
- Maintaining lists of approved medical schools;
- Appointing visitors to attend and report on examinations and medical schools;
- Recognising programmes for provisionally registered FY1 doctors;
- Controlling entry to and maintaining the medical registers together with the general function of promoting high standards of medical education and coordinating all stages of medical education.[6]

Medical trainees are provisionally registered with the GMC upon completion of their undergraduate medical school training and fully registered after successfully completing the first year of the foundation programme.

18.9 The responsibilities of PMETB were for Foundation Year 2 (FY2) onwards. They were:

- To set standards and requirements for postgraduate medical education and training leading to the CCT or equivalent;
- To secure the maintenance of those standards and requirements;
- To develop and promote postgraduate medical education and training in the UK.

2010 to 2012

18.10 Following the recommendations of Professor Sir John Tooke in 2008,[7] in April 2010 the GMC took over PMETB responsibilities and became the regulator for all training regulation from undergraduate to specialty training. The GMC published a Quality Improvement Framework in 2011 to set out how it would quality assure medical education and training in the UK from 2011–12 and is putting in place an ongoing programme of review and improvement.[8] The GMC now has statutory responsibility for setting, maintaining, developing and promoting standards of postgraduate medical education and training in the UK in addition to its original responsibilities in relation to basic medical education.

18.11 Niall Dickson, Chief Executive of the GMC, was of the view that the decision for the GMC to assume the functions of PMETB was a welcome advance. Paul Streets, Chief Executive of PMETB from January 2005 to August 2009, agreed. He said that it had removed the overlap inherent in the previous arrangements. He commented that the amalgamation made sense because the GMC can now have a continual overview of a doctor's education right from the day they start medical school until the end of their career.[9]

6 Dickson WS0000048809–10, para 52
7 Tooke et al, *Aspiring to Excellence: Conclusions and Recommendations of the Independent Inquiry into Modernising Medical Careers* (2008), www.mmcinquiry.org.uk/Final_8_Jan_08_MMC_all.pdf, p 145 recommendation 30
8 Hughes WS0000062164, paras 28–30
9 Dickson WS0000048812, para 58; Streets WS0000046508, paras 84–85

2013 onwards

18.12 From April 2013 it is intended that Health Education England (HEE), a new non-departmental statutory body reporting to the Secretary of State, will have responsibility for all NHS education and training.[10] This will be delivered through regional bodies called Local Education and Training Boards (LETBs).

Training monitoring and oversight

Undergraduate education

18.13 The GMC monitored the provision of medical undergraduate training through the Quality Assurance of Basic Medical Education (QABME) (as described below). The scheme requires medical schools to provide the GMC with an annual submission which reports changes in the curriculum and any specific risks. More information is now required than previously, and is triangulated against information from other sources.[11]

18.14 It is the responsibility of the medical schools to identify and arrange placements with providers.

Foundation training

18.15 In each foundation school there is an Associate Dean responsible for overseeing quality and performance in the training provided. They report to the head of their foundation school, who will participate in the foundation programme management group.

Specialist training

18.16 Each strategic health authority (SHA) had a deanery that oversaw the LEPs by means of a Learning and Development Agreement with each provider.[12] The Deanery also oversaw recruitment to specialty programmes in conjunction with local employers and, in the case of some specialties, with the involvement of the relevant Royal Colleges.

18.17 The Learning Development Agreement from April 2009[13] specifies standards that must be met and reporting obligations in relation to any adverse regulatory finding which may impact on the LEPs' ability to deliver the relevant training. The curriculum for each specialty is approved by the GMC (and, prior to the GMC providing approval, by PMETB).

10 *Liberating the NHS: Developing the Healthcare Workforce* (January 2012), DH gateway ref 16977, Chapter 6
11 *Quality Assurance of Basic Medical Education (QABME) Evaluation 2008/09 Cycle* (January 2012), GMC, para 16, www.gmc-uk.org/14___QABME_Evaluation_2008_09_Cycle.pdf_30067088.pdf
12 Hughes WS0000062204
13 EH/2 WS0000062217, para 9.1

18.18 Before 2005, LEPs were visited by Royal Colleges. As a transitional arrangement, some visits were continued by a few Royal Colleges after 2005 on behalf of PMETB.[14] From 2006, the head of each postgraduate specialty school was appointed jointly by the Deanery and the relevant Royal College. Before the transfer of responsibility to PMETB, in most specialties a clinical tutor was generally appointed in each trust by the relevant Royal College and the Deanery. The tutor was responsible for the management and supervision of trainees at that placement, and the trainees reported back to their college. From 2006, tutors increasingly became joint trust and school appointees reporting to the college, the school and the trust Director of Medical Education. In summary, there is still considerable variation between Deaneries and between colleges.[15]

18.19 The Government has stated that Postgraduate Deans will be the responsible officers for revalidation of trainees,[16] but the organisational structure for overseeing education and training as a whole is in transition, with the detail yet to be determined.[17]

Standards and processes

Quality Assurance of Basic Medical Education

18.20 The standards required of undergraduate medical education are set out in *Tomorrow's Doctors*, first published in 1993. The relevant edition to the period under review was issued in 2003.[18] This specified a series of curricular outcomes based on the principles set out in the GMC's *Good Medical Practice* which involve demonstrating competence in a number of fields. A number of standards were set for delivery of the curriculum. These included:

- The recognition by every doctor coming into contact with students of the importance of role models;
- The quality of teaching was to be monitored through systems including staff appraisals, student feedback and peer review of teaching.

18.21 However, the standards set down no detailed specification of where clinical teaching should take place; this was left to local decision-making.

18.22 The 2009 edition[19] of the standard is quite different in structure and tone. It set out the respective responsibilities of the GMC and the medical schools. The latter included:

14 Hughes WS0000062162, para 21
15 Hughes WS0000062163, paras 25–27
16 The Medical Profession (Responsible Officers) Regulations 2010, [SI 2010/2841], Regs 4 and 10
17 For the most detailed recent policy position see *Liberating the NHS: Developing the Healthcare Workforce – From Design to Delivery,* DH (10 January 2012)
18 ND/17 WS0000049194; the next edition was published in 2009 (see ND/17 WS0000049217)
19 ND/17 WS0000049217

Protecting patients and taking appropriate steps to minimise any risk of harm to anyone as a result of the training of their medical students.

Managing the curriculum and ensuring that appropriate education facilities are provided in the medical school and by other education providers.[20]

18.23 The responsibilities of NHS organisations included ensuring that teaching performance was subject to appraisal, support of medical schools and provision of quality control information.

18.24 In addition to outcomes for the standards, there were nine domains of teaching in which other outcomes were defined, the first being patient safety. This emphasised the importance of protecting patients from harm arising from the training of students, including a requirement for appropriately close supervision. The quality assurance domain included the requirement for systems to be in place to identify concerns about and risks to the quality of any aspect of undergraduate education, and to ensure appropriate learning opportunities in clinical placements. However, once again, there is no explicit requirement with regard to the general standards of the establishment providing the placement.

18.25 The GMC seeks to quality assure undergraduate medical training through the QABME scheme. This includes a programme of structured, announced visits to each medical school to be carried out routinely every five years. Such visits usually occur as part of a wider GMC visit during which students might be observed in clinical situations and both they and the consultants might be spoken to. The focus would be on the delivery of the curriculum, not the quality of care delivered to patients. Mr Dickson felt that a more risk-based and flexible system would be desirable where visits could be carried out more or less often if necessary.[21] However "triggered" visits can be undertaken if concerns have been raised about a medical school.

18.26 Under the scheme, medical schools are required to deliver an annual report to the GMC including any changes to the curriculum. More recently the GMC has required more evidential support to be provided. Student outcomes are measured against standards; for example, in relation to safe prescribing.

18.27 While a national UK qualifying examination has been considered, the consensus revealed by consultation has been that it would lead to a loss of diversity and flexibility in medical education, but use is now made of a shared question bank.[22] A review of this issue is planned for 2013.

20 ND/17 WS0000049226
21 Dickson WS0000048817, para 63
22 Dickson WS0000048818, para 68

18.28 There is no survey of medical students currently undertaken by the GMC, although Mr Dickson told the Inquiry that a trial is being carried out on the benefits of conducting a survey before each routine visit.[23]

PMETB/GMC quality assurance of the foundation programme standards

18.29 Standards with a similar structure to those required for undergraduates were published by the GMC for pre-registration house officers (PRHOs) in 2005 for implementation in 2007.[24] The responsibilities allocated to NHS trusts who provided training posts included making "sure that PRHOs can work safely and securely in placements where training is provided, and putting in place appropriate structures for making sure that high quality training is delivered"[25] and "providing appropriate resources, supervision, support and time for education and training to PRHOs and to those professionals involved in their training".

18.30 These standards were superseded in September 2009 by *The New Doctor*, which set out outcomes and standards for the training of FY1 doctors.[26] These followed a similar pattern to the equivalent document in respect of undergraduates (see above). Under the domain of patient safety, all doctors, employers and Deaneries, or the organisations responsible for the quality management system, were responsible for ensuring that: "The duties, working hours and supervision of trainees must be consistent with the delivery of high-quality, safe patient care."[27]

18.31 However, the criteria to be demonstrated for this standard focused on the supervision and assessment of the trainee rather than the environment in which he or she had to work.

18.32 PMETB and the GMC took joint steps in 2005/06 to put in place a structure for overseeing education and training. PMETB undertook quality assurance itself, but it expected quality management to be undertaken by the Deaneries and quality control by the LEPs.

18.33 Mr Streets pointed out that, prior to this, 17 Royal Colleges had visited training establishments, but used variable standards and methods. PMETB changed this system by introducing a common set of standards and methods.[28]

18.34 The GMC quality assured the process by examining how a Deanery quality managed LEPs. It did this by examining a sample of LEPs.

23 Dickson WS0000048819, para 72
24 ND/18 WS0000049333 – this grade became known as Foundation Year 1
25 ND/18 WS0000049350
26 ND/18 WS0000049406
27 ND/14 WS000049417
28 Streets T107.18–19

18.35 The standards were divided into nine domains: patient safety; quality assurance, review and evaluation; equality, diversity and opportunity; recruitment, selection and appointment; delivery of the curriculum, including assessment; support and development of foundation doctors, trainers and local faculty; management of education and training; educational resources and capacity; and outcomes. Of these, the following seem most pertinent to patient safety considerations:

- Patient safety:

 Patient safety is paramount. There must be clear procedures to address any concerns about patient safety arising from the training of foundation doctors immediately.[29]

 While this appears to be of generic application, the patient safety domain in this context was probably intended to apply only to the impact of the actions of trainees on patient safety. So in *The New Doctor*, published in February 2011, it was stated that: "This domain is concerned with the essential safeguards on any action by trainees that affects the safety and well-being of patients."[30]

- Quality assurance, review and evaluation:

 There must be a clear quality management system in place with standards for employers and supervisors and trainees which are fit for purpose and promote educational standards. The quality management system will demonstrate robust procedures for approving training programmes at local level and checking their quality.[31]

- Support and development of foundation doctors, trainers and local faculty:

 Support, training and effective oversight must be provided for foundation doctors. Support, training and effective oversight must be provided for local faculty.[32]

PMETB quality framework for postgraduate medical education, autumn 2007[33]

18.36 Following a series of quality assurance activities starting with its inception in 2005, PMETB prepared a quality framework after consultation, which was finally put into practice in autumn 2007.

18.37 The framework set out the main objectives of PMETB as follows:

iv. *To safeguard the health and well-being of persons using or needing the services of GPs or specialists;*

29 PS/6 WS0000046730
30 ND/19 WS0000049469
31 PS/6 WS0000046732
32 PS/6 WS0000046738
33 EH4 WS0000062309

v. *To ensure the needs of persons undertaking postgraduate medical education and training … are met by the standards it establishes;*

vi. *To ensure that the needs of employers and those engaging the services of GPs and specialists within the National Health Service and elsewhere are met by the standards it establishes.*[34]

18.38 PMETB's approach was to undertake quality assurance by way of a peer review of each Deanery and LEP against published standards and approval of programmes, curricula and assessment systems complying with the standards. This was to be achieved in the following manner:

- Approval of programmes, posts and training providers as meeting PMETB standards was to be awarded following annual visits;
- Each Deanery was to provide a self-assessment report annually together with a specified minimum data set and an action plan identifying actions taken to resolve areas of concern;
- Reports were to be obtained from each college and faculty providing details of pass rates, numbers taking examinations, and so on;
- There were to be national surveys of trainees and trainers;
- PMETB was to arrange visits to Deaneries on a routine basis and also to arrange triggered visits in response to concerns.

18.39 Quality management was to be undertaken by the Deaneries to satisfy themselves that LEPs were meeting PMETB standards. They were to:

- Be responsible for educational governance of all approved programmes;
- Adhere to PMETB standards;
- Engage in a partnership with colleges, faculties and LEPs to deliver specialty training;
- Undertake surveys not conflicting with national surveys;
- Undertake targeted and proportionate visiting of LEPs in conjunction with colleges and faculties for problem solving, improvement of education and training opportunities and dissemination of notable practice: "Wherever possible autonomy should be given to Trusts, Health Boards, and other LEPs to monitor their own performance against PMETB standards and requirements."[35]

18.40 Visits were to be advisory, to focus on quality improvement, and to be kept to a minimum and have a clear and expressed purpose.

34 EH/4 WS0000062312
35 EH/4 WS0000062319

18.41 Colleges, faculties, trainees, patients and any other interested parties were to be free to raise concerns with the Deanery or, where necessary, directly with PMETB. While setting standards PMETB did not standardise quality management methods to be used by Deaneries.

18.42 Deans have the power to remove trainees from a setting or organisation where there were "serious training concerns". Such action was to be reported immediately to PMETB and recorded in the Deanery's annual report with an action plan.[36] They can also remove approval of a training post, but not without the agreement of the GMC, or, formerly, PMETB.

18.43 Day-to-day quality control was to be the responsibility of the LEPs with a board member accountable for the function.

Quality Improvement Framework

18.44 The GMC has now developed a Quality Improvement Framework for 2011 to 2012 which sets out processes for quality assurance across all levels of medical education.[37] This document sets out four elements for achieving this:

- Approval against standards as set out in *Tomorrow's Doctors* to be complied with by August 2011;[38]
- Shared evidence including:

 Evidence from different stages of medical education training from the GMC's other functions such as registration and fitness to practise and from external sources such as health system regulators. The evidence base is being strengthened and will inform all aspects of regulatory QA.[39]

- Visits including checks which:

 "will be designed on an individual basis to reflect the differences between deaneries and medical schools and will be targeted towards areas of risk";[40]

- Responses to concerns whereby the GMC will work with partner organisations to resolve training problems before considering withdrawal of approval.[41]

18.45 This maintains the concept that: the GMC is responsible for quality assurance; the medical schools and Deaneries, with the Royal Colleges and faculties, deal with quality management; and quality control is the province of the LEPs.[42]

36 EH/4 WS0000062320, para 30
37 ND/24 WS0000049609
38 ND/24 WS0000049621
39 ND/24 WS0000049625
40 ND/24 WS0000049628
41 ND/24 WS0000049361
42 ND/24 WS0000049616

Monitoring of training

18.46 The Pro-Vice-Chancellor of Keele University and Dean of its Faculty of Health, Professor Garner, assured the Inquiry that there had been extensive mechanisms in place to monitor the training offered to students at the Trust.[43] Unfortunately, as he had not been personally involved in this function, he was unable to assist with specifics. He explained that he was not head of the medical school but had overarching responsibility for four schools and two research institutes; he suggested that the Inquiry could approach medical school staff.[44] However, the extent to which he had not informed himself of such details given the concerns uncovered about the Trust was surprising in light of his overall role at the faculty. For example, he was unable to assist the Inquiry with whether there had been any review of the systems in place following the Healthcare Commission (HCC) report or to explain why the GMC was given the impression in a letter of 24 March 2009 that the problems at Stafford were now in the past and had been resolved.

18.47 He explained that he would have expected concerns to have been raised through student feedback, and staff visits to the Trust:

- The Deanery was and is required to produce an annual report to the GMC (and before that, to PMETB). The reports were used by the regulator to evaluate the Deanery and approve them annually.[45]
- Before PMETB took over the role in October 2005, the medical Royal Colleges visited providers and had a direct relationship with the college tutor who was a college appointee. Consequently, quality issues in training were dealt with at a very local level. There was a perception that the standard of college input was variable.
- PMETB's Deanery visits were made (jointly with the GMC) to the West Midlands Deanery, following pilot visits leading to the development of quality standards in 2005/06.[46]

18.48 As of 2011 and the publication of the Quality Improvement Framework (as described above) all medical schools had been visited once since 2004; and most Deaneries had been visited three times and at least twice.[47] The GMC believes these visits have shown that quality management is maturing, but is concerned that quality control in LEPs is less developed. Therefore a yearly programme of visits was planned.

18.49 From 2008, the Deanery required LEPs to complete an annual self-assessment report. Previously Royal Colleges had made similar requirements, but inconsistently. It was expected that the LEP's clinical tutor, as a Deanery appointee, would raise any concerns identified in this way.[48]

43 Garner T107.113
44 Garner T107.115, 118, 136–137, 143–144
45 Hughes WS0000062164, para 31
46 Hughes WS0000032165, para 32; PS/6 WS0000046728
47 ND/24 WS0000049629, para 100
48 Hughes WS0000062173, paras 67–69

Conclusions

18.50 As stated above, this Inquiry's interest in medical education and training is limited to its impact on patient safety and the contribution its quality assurance and management systems can or could make to detecting and remedying deficiencies in compliance of providers with fundamental patient safety and quality standards. Therefore, a detailed textual and systems analysis is not appropriate. However, the voluminous documentation on quality assurance and management published during the period under review presented to this Inquiry, whether emanating from PMETB or the GMC, has failed to demonstrate an adequate recognition of the role these activities should be playing in safeguarding patients.

18.51 Understandably there has in the past been a focus on the potential risk to patients presented by students and trainees. To that end, and very properly, standards have required adequate supervision support and so on. What has received less emphasis has been the risk that can be presented to patients by placing students and trainees with an LLP that does not comply with minimum safety and quality standards. While all registered medical practitioners are obliged by the GMC's *Good Medical Practice* to make the care of the patient their first concern, inevitably trainees are likely to be less able to detect and address any risks arising, and thereby to protect patients, than more senior colleagues should be able to do. Their training will suffer in such surroundings, but more importantly the patient may suffer as well.

18.52 Further, any registered practitioner participating in the quality assurance and management systems, by, for example, participating in a visit to a hospital, is under an obligation to protect the health of patients where he or she becomes aware of a risk. The monitoring of education and training offers opportunities for gathering information which is relevant to an organisation's compliance with fundamental safety and quality standards from direct observation; questioning of students and trainees; analysis of systems and outcomes of supervision; appraisal; and other data. This is not to suggest that direct observation and questioning of trainees should form the exclusive basis of a quality assurance system. This had been identified by the Bristol Inquiry as a deficiency. However, as the experience at the Trust shows, there is every reason why these tools should continue to be part of the monitoring process to have proper regard for patient safety.

18.53 Therefore the system of visits and assurance generally needs to take into account these obligations and how they should be met. None of the frameworks or standards applied during the period under review appear to have achieved that.

18.54 This does not mean that education and training regulators are obliged to duplicate the work of healthcare regulators, but neither does it mean that it is always safe merely to rely on an assumption that such a regulator will deal with systemic or other risks to patients. A few simple principles need to be incorporated into the education and training system:

- The system of medical training and education must keep as its first priority the safety of patients.
- No provider of clinical placements should be permitted to receive or employ students and trainees in areas or services not complying with minimum patient safety and quality standards.
- The regulators and Deaneries should, as part of their monitoring of the standards of education and training provision, assess and exercise an independent judgement whether providers comply with the above principle.
- If, in the course of any quality assurance or management process, concerns relating to patient safety are raised or become apparent, whether or not directly relevant to the well-being of students or trainees, appropriate action must be taken to ensure that the concerns are properly addressed and the health regulator informed.

18.55 A challenge which the GMC recognises is that the standard of both care and training can vary considerably between departments in the same establishment. It has suggested, however, that there is no clear relationship between the quality of care and the quality of training. Judged from trainee feedback, which has not always raised concerns about the quality of care, that may be true. That should not, though, be taken to mean that it is acceptable for training to take place in a training environment in which poor standards of care persist.

18.56 Since the events at Stafford the GMC has taken a number of steps to increase the focus on patient safety in its assessments of training:

- In 2012 a specific patient safety question was introduced into the National Trainee Survey. Of a very high rate of responses (95% of trainees), 4.7% (2,400 trainees) reported a patient safety concern, of whom 23% had not previously reported this locally, and of which Deaneries and the GMC were previously unaware.[49]
- The GMC has created a "Responses to Concerns" process through which steps are taken to address reported concerns. A clinical assessment team can be, and is, deployed at short notice to investigate concerns at a local level, support Deans, and provide observers on Deanery-led visits to provide assurance to the GMC that local systems are working.[50]
- As a result of reported concerns, the GMC has launched an audit of all emergency department rotas in the UK where foundation doctors are trained. Instances have been found of such trainees not being provided with adequate supervision, and action has been demanded within 48 hours.

18.57 These steps are encouraging, and have clearly brought to light information which is of concern and appears to confirm the need for the principles described above to be applied rigorously.

49 *National Training Survey 2012: key findings*, GMC, www.gmc-uk.org/education/surveys.asp
50 Further detail on this process is available at: www.gmc-uk.org/education/process.asp

West Midlands Deanery

18.58 There are generally about 6,000 trainees in the West Midlands region. Trainees are distributed around 15 acute provider trusts; 4 specialty trusts; 7 mental health trusts; and 17 PCTs in 5 clusters. During the period under review (January 2005–March 2009) the Deanery was accountable to PMETB, thereafter to the GMC for medical trainees and the General Dental Council (GDC) for trainee dentists. In 2006, the Deanery was merged with the West Midlands Strategic Health Authority (WMSHA).[51]

18.59 At the beginning of the period under review the regional Dean was Professor Stephen Field. In October 2007 Dr Elizabeth Hughes became Acting Dean, as Professor Field had been elected Chairman of the Royal College of General Practitioners. He did not relinquish the substantive post of Dean but, due to his other commitments, only undertook about 40% of the role. Professor Hughes also had other roles.[52] This arrangement continued in practice when, in March 2008, Professor Hughes was also appointed to the substantive post, until June of that year when she took over full responsibility for the post.

18.60 To her credit Professor Hughes has offered no suggestion that the performance of the Deanery in relation to the matters under review was other than her responsibility, or that her role was hindered by this job-sharing arrangement. However, it is difficult to believe that this important role would not have been performed more effectively by a single appointee who did not have a shared responsibility with a colleague who was largely absent from it.

Approved practice settings

Scope of scheme

18.61 An approved practice setting (APS) is a setting:

- *Where [the practitioner] is subject to a governance system that includes but is not limited to provision for appropriate supervision and appraisal arrangements or assessments; and*
- *Which is, or which is of a type which is, for the time being recognised by the [GMC] ... as being acceptable for a practitioner who is newly fully registered.*[53]

18.62 The intention was that a post for a practitioner who is newly fully registered should have a supportive environment in place during their first year of practice rather than being simply able to set up fully in practice on their own account without managed and supportive structures, and that this would only apply to a limited class of practitioner.[54] The GMC has

51 Hughes WS0000062159, para 5
52 Hughes WS0000062158, para 4.5
53 The Medical Act 1983, section 44D(1) inserted by The Medical Act 1983 (Amendment) and Miscellaneous Amendments Order 2006 (SI 2006/1914), Art 70
54 Dickson WS0000048796, para 13

never regarded the APS scheme as being intended to provide any form of quality assurance of the medical education and training provided.

European Economic Area practitioners

18.63 In October 2007, in place of a concept of limited registration for overseas practitioners which was regarded as discriminatory, a new registration framework was introduced by the GMC[55] under which medical graduates (both from the UK and overseas, and those returning to practice after a break) are required to work in an APS for the first 12 months. Graduates from the European Economic Area (EEA) are "strongly advised" to commence practice in an APS. Mr Dickson understood that the European Union (EU) had sought to persuade the GMC to remove this advice.[56] In any event, in spite of this "advice", in law EEA practitioners can begin practice in the UK without starting in an APS. Mr Dickson voiced concern that the current requirements for proof by international medical graduates of proficiency in the English language could not be applied to EEA practitioners.[57]

18.64 While it would be fair to say that there was little if any evidence of this being an issue in Stafford, it is a matter of serious concern with regard to the safety of patients that it is possible for them to be exposed to the care of a medical practitioner without a sound practical ability to communicate in clear English, regardless of his or her origins.

18.65 Mr Dickson told the Inquiry that the GMC was in "negotiation" with the Government on this issue. If the focus is on seeking changes in EU law, it may be that this is missing the point. It is not just doctors from Europe who should be required to have this proficiency, it is all doctors. There is no reason why proof of this should not be a general requirement. It may be that the practical difficulties of requiring all to take a special examination or test in their proficiency in English could be avoided by a recognition of a variety of equivalent qualifications commonly held in any event by practitioners with the relevant standard of proficiency.

Approach to the regulation and oversight of approved practice setting establishments

18.66 Mr Niall Dickson, Chief Executive of the GMC, asserted, on the basis of legal advice received by them, that it had no power to quality assure these establishments itself, pointing to section 44D(6)[58] of the Medical Act 1983 which gave, as an example of a valid reason for withdrawing recognition from a practice setting, the absence of quality assurance of its governance system "by a body that is acceptable to the [GMC as a provider of quality assurance]".

18.67 He stated that they had no powers of audit or inspection and relied on assurance given by others, including the HCC (now the Care Quality Commission or CQC). Information from the

55 Dickson WS0000048795, paras 11–12; Medical Act 1983, section 44D; ND/2 WS0000048914
56 Dickson T105.14–25
57 Dickson T105.13
58 Inserted by The Medical Act 1983 (Amendment) and Miscellaneous Amendments Order 2006 (SI2006/1914), Art 70

regulators is triangulated with trainee and trainer surveys, and information from Deaneries, although organisations are not approached "systematically" for this purpose.[59]

18.68 The GMC has continued to adopt the same approach to assessment of APSs by reliance on CQC assessments. They have sought to "map" their APS criteria to CQC standards.[60]

18.69 While the Inquiry accepts Mr Dickson's evidence about the legal advice received, if the GMC is to have power to consider whether an organisation should be recognised it should be empowered to take such reasonable steps as it considers necessary to make any required assessment. Section 44D(5) is in very broad terms:

> *The General Council may at any time vary or withdraw their recognition from a particular practice setting or a particular type of practice setting.*

18.70 It would be surprising if section 44D(6) referred to above were to be construed so as to prohibit the GMC from regarding itself as an "acceptable" body for this purpose. There seems no reason in any event why it could not commission an external body to undertake this task. Further, while the statute gives no specific power of audit or inspection, if it were reasonable to request access for these purposes, a refusal to grant it might be considered a reason not to recognise an establishment. In short, the GMC may have been taking too narrow a view of what it could do to fulfil its statutory functions in relation to APSs. To the extent that there were and are understandable concerns about proportional use of resources, there would appear to be no reason why the relevant monitoring could not be undertaken with that required for other areas of oversight of medical training placements.

Approved practice setting criteria

18.71 The GMC has formulated criteria for acceptance as an APS.[61] The criteria include:

- Regulation or quality assurance by an independent body or organisation;
- Effective management of doctors through appraisal or assessment of individuals based on the GMC's *Good Medical Practice* guidance;
- A system of clinical governance or, if outside the NHS, a quality assurance system, with clear lines of responsibility and accountability for the overall quality of medical practice, clear policies aimed at managing risks, and appropriate supervision arrangements for doctors;
- Identification and action on concerns about doctors' fitness to practise;
- Acting on and learning from complaints;
- Support for the provision of continuing professional development;

59 Dickson WS0000048796–801, paras 13, 19, 23, 28
60 Dickson T105.21
61 ND/3 WS0000048923–4

- Respect for human rights;
- Identification and management of staff not complying with GMC guidance.

18.72 Mr Dickson appeared at first to be content with this system:

> *I do not think that it is for the GMC to look behind other organisations' processes such as the HCC's Annual Health Check, and we also do not have powers to do this beyond having an understanding of the checks being carried out. However, if we have concerns about the way the systems regulator is providing assurance, that is something we would discuss with them, if we are having to rely on that assurance.*[62]

18.73 However, he agreed that the HCC, and now the CQC, had little in their regulatory framework which specifically related to medical training. The GMC sought to "map" reported changes in compliance to the APS criteria.[63] He agreed that this was not satisfactory:

> *I think for the future, I would like to see a different system, because we are not a systems regulator. What we are doing is checking a system regulator's work and then trying to nudge people along to make them a bit more compliant to what the system regulator should be doing anyway. I don't think that's the right way to go about this problem, and I think there is a problem, particularly of doctors who are arriving in this country from overseas who haven't had the support that they've needed historically from the NHS, but – and obviously we want them to work in a managed environment.*[64]

18.74 He conceded that the APS system had not been satisfactory, although it had achieved an objective in not allowing newly arrived doctors to "go off and do their own thing".[65]

18.75 He thought that the newly appointed responsible officers, who will have the duty of overseeing registered medical practitioners' revalidation, could be given the additional responsibility of offering direct support to the individual practitioners.[66]

18.76 It is clear that within the GMC there has been a sense of unease at the extent to which it has to rely on the assurance work of other organisations, both in relation to APS and revalidation. At a council meeting in March 2009 the issue of the APS status of the Trust was discussed. On the basis of reports by then published it was accepted that its adequacy as an APS was called into question.[67] Mr Finlay Scott, then GMC Chief Executive, reported that the GMC had written to the Trust seeking "confirmation of the agreed changes to address the Healthcare

62 Dickson WS0000048799, para 21
63 Dickson T105.21
64 Dickson T105.21–22
65 Dickson T105.24
66 Dickson T105.25–26
67 ND/5 WS0000048954

Commission's concerns, in order that we can be satisfied that it would remain an appropriate place to be designated as an [APS]".

18.77 A problem identified in relation to both APS and PMETB approval systems was that withdrawal of it was a "blunt instrument" and would have a serious impact on the delivery of healthcare. Mr Scott pointed out that the ability of the GMC to do the regulators' job was limited because of the large numbers of organisations involved. However, he went on to say that:

> *We clearly cannot be in a position, either in relation to* [APS] *or, more importantly, in relation to revalidation, where we are prepared to rely on certification produced locally without confidence that the systems providing the certification are robust.*[68]

18.78 Mr Dickson, who was not at the GMC at this time, agreed that this concern persisted:

> *It is a legitimate concern and it – it still persists, in as much as we have not yet, but I – I believe that we ought to be able to get to that position, where we can have an engagement with CQC and have confidence that the things that they're doing will give us the assurance that we need in relation to revalidation.*[69]

18.79 He also echoed the observations of Mr Scott about the difficulties in withdrawing approval. He pointed out that withdrawal would cause great difficulty to FY2 doctors and might be considered disproportionate.[70] Although the GMC had in the past withdrawn approval from three APSs, on the whole this was very difficult where a hospital was still functioning and authorised to continue by the regulator.

Monitoring of the Trust's compliance with approved practice setting criteria, 2007 to 2009

18.80 The GMC's registration committee awarded APS status to the Trust and 218 other trusts in September 2007. The committee relied on the HCC's Annual Health Check (AHC) ratings published in 2006 and the Trust's AHC self-declaration for 2007.[71] Trusts reported by the HCC as compliant with the core standards were automatically awarded APS status.[72] Trusts not compliant were invited to provide evidence of the steps they were taking to achieve compliance and the award would be made if they could show plans were in place to address outstanding areas of concern. Confirmation of full compliance would be sought at the next assessment. Even this somewhat remote approach to assessment was challenging to the resources of the GMC, as a result of which it was thought: "our plan to exploit the processes

68 ND/5 WS0000048957
69 Dickson T105.25
70 Dickson WS0000048806, para 43; Dickson T105.50
71 Dickson WS0000048805, paras 39–40; ND/8 WS0000049031–2, paras 11, 18
72 ND/8 WS0000049031, para 11; Dickson T105.15

used by the quality assurance bodies across the UK will limit our role to engaging only with those institutions that are non-compliant with our APS criteria."[73]

18.81 Therefore the assessment system was entirely dependent on the accuracy of the HCC's assessment, and the reliability of the self-assessment and declaration of the trusts themselves, albeit with a degree of comfort to be obtained from the third party commentaries which were an obligatory part of the self-declaration. As can be seen from the commentaries provided in the case of the Trust's declarations, these could be far from informative.

18.82 This approach was informed by the GMC's view that it was not a systems regulator and that it would have been a mistake to try to become one.[74] However, this effectively delegated assurance to the formal processes of the HCC, which had no responsibility for monitoring the suitability of establishments for training purposes, save to a limited extent.

18.83 With regard to the Trust, it is not entirely clear why it was passed at the first assessment in September 2007 with a clean bill of health by the GMC:

- In the 2005/06 AHC the Trust had declared non-compliance with standards relating to professional development and updating of clinical skills, presumably important concerns relevant to the suitability of the Trust as a training establishment.
- In 2006/07 the Trust had declared insufficient assurance in relation to mandatory training programmes, also an obviously relevant matter.

18.84 As no further information was looked at, the GMC did not take into account any of the concerns which arose about the Trust in 2007, in particular the high Hospital Standardised Mortality Ratio (HSMR) reported in April 2007, or the increasing concerns of the HCC which led eventually to the announcement of their investigation in 2008.

18.85 The Trust's status was reviewed after the publication of the 2007/08 AHC assessment in October 2008.[75] According to Mr Dickson, the Trust's APS status was continued because it was reported by the HCC to be compliant with the core standards. This failed to take into account the fact that the HCC rating was provisional. Given the lack of prominence the HCC gave to this fact this is not a surprising omission. However, the GMC's approach meant that it failed also to take into account the announcement of the HCC investigation or any information about the serious concerns uncovered by October 2008, which it might have gathered if it had made appropriate inquiries of the HCC, the Postgraduate Deanery and PMETB.

73 ND/8 WS0000049035, para 28
74 Dickson T105.17
75 Dickson WS0000048805, para 40

GMC monitoring of Trust compliance after the Healthcare Commission report

18.86 Following publication of the HCC report in March 2009, the Assistant Director of Registration of the GMC wrote to the Trust.[76] The letter referred to the report's recommendations concerning the arrangements for overseeing the quality and safety of clinical care; staffing and capacity; training and supervision of junior doctors; and support from the intensive care service. In the face of these concerns the position taken by the GMC was expressed in surprisingly relaxed terms:

> *I appreciate that since the matters were formally raised by the Inspectors, changes to address the concerns identified may already have been implemented. Nevertheless, we are obliged to assure ourselves that the Trust continues to be compliant with our approved practice setting criteria.*[77]

18.87 The Trust was merely requested to provide a copy of the changes agreed with the HCC to address their concerns and a status report on their implementation.

18.88 This was an entirely inadequate response to the enormity of what had been revealed. The HCC report contained ample evidence that the Trust did not "continue" to be compliant with APS criteria, and indeed could not have been compliant at the time of the renewal of APS status the previous year. Without an immediate and direct inquiry at the Trust, the GMC had no means of knowing whether any registrants were prejudiced by remaining in an environment incapable of fulfilling the objectives of the scheme. The GMC had a responsibility to ensure that it was not permitting newly registered doctors and newly arrived overseas doctors to be exposed to circumstances in which their ability to protect patients in accordance with *Good Medical Practice* was compromised. It should have been crystal clear from the HCC report that reliance on self-declarations of this Trust at least was not a reliable means of assessment. Yet the only immediate step taken was to ask the Trust for assurances. Even if the GMC's somewhat restrictive view of the remit of APSs was appropriate, the HCC report showed that the Trust was unlikely to be "acceptable" as a placement.

18.89 A response was received from the Trust exactly one month later, enclosing the latest version of the Trust's Improvement Programme Plan.[78]

18.90 In a memorandum[79] dated 14 May 2009, now two months after the publication of the HCC findings, the plan was considered, and it was concluded that it showed that:

76 Dickson WS0000048805, para 41; ND/9 WS0000049048
77 ND/9 WS0000049049
78 Dickson WS0000048805, para 41; ND/10 WS0000049052
79 Dickson WS0000048806, para 42; ND/11 WS0000049057, para 5

... the Trust have responded to the [HCC]*'s recommendations by putting plans in place which will enable them to address the concerns raised in the report. They have identified appropriate milestones to enable them to achieve their goals, with a view to all recommendations ... to be achieved by March 2010.*

18.91 It was recommended that the Trust be permitted to retain APS status but that it would remain under review until the planned objectives had been achieved; and further status reports would be requested in future, the first being due in October 2009. The report was accepted and, on 22 May 2009, the decision was communicated to the Trust.[80] The Trust was reminded of its responsibility to ensure that it remained compliant with the APS criteria, and was required to inform the GMC of any changes relevant to APS status. They were told it was "likely" that the first review would be in October 2009.

18.92 No review was carried out in October 2009, the next request for an update being in February 2010. Mr Dickson recognised that this was unfortunate and attributed it to the GMC's APS systems not being as robust as he would have expected. He thought that the main reason for this was difficulty in matching the CQC's standards to the APS criteria, a process which was only completed when he ordered a review which was finished in November 2010. In his oral evidence he explained:

The reality is that the team that was responsible for APS got, I think, confused, is probably the best word, between the transfer between the Healthcare Commission and the Care Quality Commission, and didn't follow up reviews, including this one. And it wasn't just this one that was not followed up. And there was a gap in our systems, which enabled that to happen, without it being spotted. And I have now taken action to rectify that. So there was a period during which we didn't run the APS system effectively. This is part of it.[81]

18.93 It is no coincidence that the renewed interest in the Trust occurred shortly after Mr Dickson's arrival at the GMC in January 2010. Disciplinary action was taken in respect of reviews which had not been carried out.[82]

18.94 It is not clear that any response was received from the Trust to the request made in February 2010, as the GMC wrote again in August 2010 in terms implying that it had not received a response.[83] This time Mr Obhrai, Medical Director at the Trust, replied sending a copy of a report to his Board on progress. This noted that 23 out of 24 objectives scheduled for completion had been achieved, but that the target of 100% staff appraisals had not been reached. Of the objectives scheduled for completion in the following quarter, 5 out of 33 were

80 ND/12 WS0000049059
81 Dickson T105.58
82 Dickson WS0000048804, para 36; WS0000048806, para 42
83 ND/13 WS0000049063

at risk of non-completion. The report included implementation of the recommendations of the first inquiry.

18.95 A further update was sought in November.[84] The GMC noted in sympathetic tones that the Trust must have been busy with the Inquiry, and that CQC had reported in October that encouraging progress was being made. However, it was also noted that areas of minor and moderate concern remained. The update was requested to enable the GMC to assess which areas of concern remained outstanding. In the meantime APS status was to be continued. The Trust was reminded of the GMC's powers but was reassured it was unlikely to use them:

> *The GMC does ultimately have the power to vary an organisation's approved practice setting status or, if necessary, to remove it altogether, but I am confident that we will not need to consider such action given the serious implications it would have on the Trust's ability to appoint newly registered doctors.*

18.96 The Trust responded in December 2010, supplying an update on progress, and the GMC resolved to continue APS status and stated it would be seeking an update early the following year. This process was repeated in March and May 2011.

18.97 As a means of ensuring that an establishment could achieve the objectives of APS status, the immediate approach taken by the GMC, even after realisation of the very serious concerns about the Trust, was deficient in a number of respects:

- There was no liaison with the HCC or its successor, the CQC, to confirm whether it considered the programme adequate.[85]
- No contact was made with any doctors in the scheme to determine whether patient safety was compromised in any way by the continuance of APS status.
- There was no recognition of the relevance of continuing non-compliance with APS criteria until the plan was completely implemented. For example, at the time of the October 2009 review, the programme to develop an open culture had not even started at this point and was intended to increase incident reporting activity only by March 2010. It was intended that changes in clinical practice required by a "timely and thorough" review of serious untoward incidents (SUIs) would occur by September 2009, ie in four months' time. While a "realistic and deliverable" clinical audit plan was to be in place by June, an audit of that process did not have to be completed until January 2010. The programme left open the possibility of understaffing until March 2010. The plans for effective management of junior doctors did not have to be in place until October 2009. Given where the new management at the Trust was starting from, such time lags may have been inevitable, but they meant that newly fully registered doctors who should have had 12 months' experience in a

84 ND/13 WS0000049080

85 Since these events, the GMC has been undertaking work with the CQC to develop an operational framework which sets out the practical steps required of each organisation in sharing information and coordinating activities. This is expected to be in place by the end of 2012.

setting meeting certain criteria were going to have to endure a substantial part, if not the whole, of that period in one not meeting them. For such doctors, permitting them to remain at the Trust must have defeated the primary object of the scheme, as with all the functions of the GMC, of protecting patients.

Conclusion

18.98 The APS scheme was intended to ensure that practitioners who are newly fully registered and newly arrived doctors from outside the EEA practised for 12 months in an environment where they could be properly supervised, appraised and introduced in a safe environment to independent professional practice. It should have been an important safeguard for patients. The GMC was given responsibility for setting relevant standards, approving establishments for this status and monitoring compliance. While the GMC approached this scheme on the assumption that it did not extend to a power to quality assure medical education and training, such a power was not needed to ensure that doctors were provided with a safe and "acceptable" environment in which to receive education and training. The GMC's approach to this task was to rely entirely on self-assessments by the organisations they were meant to be monitoring and the healthcare systems regulator. It was an approach driven no doubt by considerations of available resources and proportionality, but was without meaning or effect. It resulted in APS status being given and maintained for a trust which, on the evidence available, was not compliant with the GMC's criteria at the time of initial approval, and may well have remained non-compliant at the time of the oral hearings in this Inquiry. No adequate additional steps were taken to address the clear evidence of non-compliance reported by the HCC. There was no appreciation of the need for urgent and proactive review and the exercise of independent assessment of the situation in the interests of protecting patients and newly qualified doctors. At no time was serious consideration given to withdrawal of approval or any lesser intervention. There seems to have been a concerning lack of liaison during the period reviewed with CQC or other bodies for the exchange of information and cooperation in joint regulatory approaches.

18.99 The evidence from the GMC suggested that it was continuing the approach of relying on the healthcare systems regulator and assurances from the approved establishments. The experience of Stafford has demonstrated that this is insufficient protection for patients and the public.

18.100 The GMC has been reviewing the APS scheme to consider what changes are required. On 14 December 2011 the GMC Council resolved to seek Government support to overhaul or remove the APS provisions once the revalidation scheme had been fully implemented. It considers that in this new environment an APS scheme, entirely separate from the revalidation requirements and the structure of responsible officers, offers little added value. In the meantime, the GMC is auditing compliance with APS requirements, and reviewing

quality assurance processes to consider whether the lessons from this Inquiry have been incorporated.

18.101 While the involvement of responsible officers may be an improvement, it is not sufficient. Responsible officers will usually be the medical directors or other senior clinicians employed by the establishments under scrutiny. They will have onerous responsibilities with regard to the appraisal and revalidation of all medical practitioners in their organisation. While they may well have a positive effect on the implementation of expected standards of professional scrutiny, there is an inherent conflict in imposing on them an additional role of representing the GMC as a regulator. The Stafford experience shows that the personal professional obligations of a medical director under GMC requirements are no guarantee that concerns are raised and addressed appropriately.

18.102 The lack of a choice of a realistic range of interventions may be a factor inhibiting the GMC from a prompt and strong reaction to evidence of non-compliance. The power of removing approval is considered to be a "nuclear" option because of the potential impact on the organisation, its patients and junior doctors. Provision needs to be made for a range of lesser interventions, such as imposition of conditions, restrictions on the services in which new doctors can be placed, provision of support for new doctors and so on.

18.103 Special consideration needs to be given in any new scheme to the particular position of newly fully registered and newly arrived doctors. They are particularly vulnerable to being misled by poor practice; to pressure, whether intentional or institutional, not to raise concerns; and to a general compromise of their professional position. It is difficult to see how, without the regulator exercising effective powers of quality assurance of education and training, new doctors can be protected to ensure that what is delivered protects their own position as well as the safety of patients.

PMETB/GMC Quality Assurance of the Foundation Programme – 2006 "pilot" visit to West Midlands Deanery

18.104 The foundation programme consisted of the training in FY1, set and assured by the GMC, and that for FY2, set and assured by PMETB. The programme started in August 2005, just before PMETB assumed its formal powers in September 2005. In the same month the GMC and PMETB launched a joint Quality Assurance of the Foundation Programme (QAFP) to determine the appropriate methods of quality assurance and to develop a joint process. A "pilot" programme was pursued during 2005/06. It was intended to ensure a free flow of information to regulators and Deaneries to support mutual improvement of standards.[86]

86 Streets WS39 WS0000046494, para 39; PS/6 WS0000046728, para 2

18.105 In February 2006, PMETB and the GMC conducted a Deanery-wide visit to the West Midlands. This was part of a pilot scheme, the purpose of which was to assist in the production of standards and methods of quality assurance by inspecting the Deanery against draft standards.[87] In the report the visiting team set out their findings against the draft standards. The team visited the Deanery and three trusts (not including Mid Staffordshire) and met a number of Deanery leaders, clinical tutors, supervisors, medical directors and trainees. A summary of the team's findings in relation to some domains follows:

- Patient safety domain

 Patient safety is paramount. There must be clear procedures to address any concerns about patient safety arising from the training of foundation doctors immediately.[88]

 The visiting team heard of three instances where doctors were said to be inadequately supervised and fed this back immediately so that prompt action could be taken. It was thought this was more likely to occur in specialties with no previous experience of training pre-registration Senior House Officers (SHOs), whose permitted activities were similar to those of FY1 doctors.[89] On following this up the Deanery expressed itself satisfied that FY1 doctors were being adequately supervised.[90]

 The visiting team reported variable awareness of whistleblowing policies among foundation doctors spoken to, and found that, in general, whistleblowing was not specifically addressed in core curriculum teaching.[91] It was recommended that communication of whistleblowing policies to trainees be implemented and clarified.

- Quality assurance, review and education domain

 There must be a clear quality management system in place with standards for employers and supervisors and trainees which are fit for purpose and promote educational standards. The quality management system will demonstrate robust procedures for approving training programmes at local level and checking their quality.[92]

 The team noted the Deanery was monitoring quality through annual visits to each foundation programme after which recommendations for improvement were made. If components required improvement, conditional approval only was granted. Highlighted issues were included on a database available to trust chief executives, and put into the public domain. The operation of this system was confirmed during visits to the hospitals. The team recommended that the trust management had to take responsibility for monitoring and managing the quality of education provision and should be setting standards in accordance with those set by the Deanery.[93]

87 PS/6 WS0000046728–30
88 PS/6 WS0000046730, para 12
89 PS/6 WS0000046730, para 14
90 PS/6 WS0000046749
91 PS/6 WS0000046731, para 18
92 PS/6 WS0000046732
93 PS/6 WS0000046744, para 102

- Support and development of foundation doctors, trainers and local faculty

 Support, training and effective oversight must be provided for foundation doctors. Support, training and effective oversight must be provided for local faculty.[94]

 The team observed that foundation doctors whom they approached felt able to raise concerns if they felt bullied or harassed.

18.106 Overall the team came to positive conclusions and was satisfied that the Deanery met the standards for foundation training.

18.107 It was commendable that the draft standards gave the highest priority to patient safety and that immediate action was taken in respect of the matters relevant to this which they found. As this was a pilot scheme, the standards were new and not finalised, and the visit did not extend beyond meeting trainees and trainers, it was inevitable that the focus was on the interaction with trainees, rather than the environment in which they were being trained.

PMETB/Royal College of Physicians approval visit to the Trust, March 2006

18.108 Over a period of two days in March 2006 a three-person team from the Royal College of Physicians visited the West Midlands region on behalf of PMETB. Paul Streets, then the Chief Executive of PMETB, could not recollect the reason, but presumed it was a risk-based visit. The purpose of the visit was to review existing training approval on its expiry, and the team reviewed posts at no less than 16 trusts, including Mid Staffordshire.[95] They considered a range of documentary evidence and interviewed 134 people, including 70 specialist registrars (SpRs), 21 college tutors, and 36 educational supervisors. The report was generic in nature but did mention specific concerns about some hospitals by name. The Trust was not among these. Indeed, it was among those "commended" for its supervision. The concerns potentially indicative of risk to patients raised by this team about trusts other than Mid Staffordshire included:

- SpRs carrying out a "very large service element" with limited consultant supervision;
- SpRs isolated and unsupported at night;
- Lack of clear structure to the SpR role;
- Abolition of a medical unit against national trends and expert advice;
- Lack of clinical leadership.

18.109 The inclusion of the last criticism suggests an inspection which goes beyond the narrow confines of the trainees' experience to a consideration of whether the hospital was a safe

94 PS/6 WS0000046738
95 Streets WS0000046483, para 63; PS/9 WS0000046803

or desirable one for trainees, and whether its standards were appropriate for a training establishment.

Problems caused by the introduction and abandonment of the medical training application process

18.110 In 2007 the Deanery was likely to have been preoccupied with the problems surrounding the medical training application process (MTAS), as was the entire training system. A flavour of the impact of this can be gleaned from the report of a PMETB visit to the Deanery in March 2007:

> *The ... Deanery was in the middle of the MMC interview process during the week of the visit. This new (UK-wide) process has relied upon an electronic recruitment platform (MTAS), and the introduction of new short-listing and interview (selection) methodology. Unfortunately the very large number of applicants for specialty and general practice training has created tremendous pressure on all deaneries and their staff. The significant amount of adverse publicity has also generated much anxiety, particularly amongst doctors applying for training opportunities and many NHS consultants.*[96]

18.111 It is unnecessary to go into the protracted history of MTAS, but the problems experienced resulted in an independent inquiry being set up under the chairmanship of Professor Sir John Tooke in April 2007 by the Secretary of State. The scale of the immediate effort required to correct the problems can be gauged from the introduction to the inquiry's interim report:

> *Whatever else this Inquiry achieves, the distress caused to the next generation of specialists and senior doctors must never be repeated. We should also acknowledge the exceptional efforts of consultant clinicians, postgraduate deaneries, Trust HR Departments and the Review Team in their attempts to handle the crisis and ensure that the impact on service was contained. It is a testament to their commitment that this was indeed the case and that most specialist training posts were filled.*[97]

18.112 The report described the episode as "deeply damaging".[98] The British Medical Association (BMA), endorsed by a High Court Judge, described it as a "dreadful mess".[99]

18.113 The Inquiry has been advised by two of the assessors that in their personal professional experience these difficulties were suffered in extreme form throughout the country and

96 PS/11 WS0000046863, para 10
97 Tooke et al, *Aspiring to Excellence: Conclusions and Recommendations of the Independent Inquiry into Modernising Medical Careers* (2008) p12 – the interim report was delivered in July 2007 but included in the final report, www.mmcinquiry.org.uk/Final_8_Jan_08_MMC_all.pdf
98 Tooke et al, *Aspiring to Excellence: Conclusions and Recommendations of the Independent Inquiry into Modernising Medical Careers* (2008), p15, www.mmcinquiry.org.uk/Final_8_Jan_08_MMC_all.pdf
99 R (Legal Remedy UK Ltd) v Secretary of State for Health, PMETB and others [2007] EWHC 1252 (Admin) Goldring J, para 2, www.bailii.org/ew/cases/EWHC/Admin/2007/1252.html

resulted in Deaneries having to devote a substantial part of their resources to remedying problems. It is not part of the Inquiry's remit to investigate this episode but it is clearly relevant as a factor likely to distract training overseers from monitoring and quality assurance activities.[100]

Keele University Medical School

18.114 Keele University Medical School delivered Manchester University's undergraduate medical degree. In his statement to the Inquiry, Professor Garner explained that the School placed small numbers of students with the Trust from 2006 and more extensively from 2008,[101] although some students were also placed earlier as part of the 2003–2005 collaborative Manchester curriculum. From 2011/12 the Medical School will deliver in addition its own primary medical degree. It placed 47 students at the Trust in 2006/07; 86 in 2007/08; and 90 in 2008/09, for an annual total of student weeks of between 234 and 480.[102] Throughout this period it considered the placements to be satisfactory. Feedback from students was described as positive and no feedback with regard to the quality of care was received.

18.115 Plans to place students into clinical settings focused in the first instance on whether an organisation had sufficient facilities and services fitting the content of the school's proposed medical curriculum.[103] When asked about the mechanisms in place in 2008 to assess the quality of care being provided at Mid Staffs, Professor Garner, who was Dean of the Faculty of Health and Pro-Vice-Chancellor, told the Inquiry that he believed the mechanisms in place were "really quite extensive" and included reporting from students, visits by medical staff and inspections by the GMC.[104] However, it appears that although feedback could be provided by students, it was not actively sought in relation to the broader questions of patient care outside of the immediate context of quality of training. The main aim of feedback was "to monitor the educational experience from the perspective of an undergraduate medical student".[105] Nor was feedback sought from outside the student body through staff surveys available in the public domain.[106] Professor Garner accepted that the School was principally

100 Evidence cited in the Legal Remedy case from the West Midlands Deanery did not suggest they perceived the problem to be as serious: [judgment para 44]
"There were some but not universal problems with interviews. The only ones not completed were in surgery, where the surgeons were so concerned about the situation that they walked out. The surgical consultants wanted an immediate suspension of round one. Feedback from interview panels was that despite concerns it was possible to select some excellent candidates. The mood is lifting in the consultants who have seen the interview process in action." Professor Field of the West Midlands Deanery concluded by saying: "We have debated the situation at length and believe we should proceed with the round one interviews but we must make changes for round two. We do not believe interviewing all applicants for round one is feasible. We do not believe that it would be supported by the service ...
"... The shortlisting criteria need reviewing e.g. more marks for academic excellence, more discriminatory questions and better instructions to help assessors give marks is essential ..."
However, this did not address the impact on the other work of the Deanery.
101 Garner WS0000050356/358, para 8
102 ND/30 WS0000049705
103 Garner T107.109
104 Garner T107.113
105 AG/12 WS0000050469
106 Garner T107.118

reliant on students for information as to what was going on at the Trust,[107] but that that feedback had failed to raise any concerns in relation to the Trust when there clearly were problems.[108] There were other limited sources of knowledge of concerns available to the University. Professor Garner had been aware before publication of the HCC report of emerging reports of high mortality rates as the topic had been discussed openly locally, for example as part of board meetings at the University Hospital of North Staffordshire.[109] The Medical School was also represented on the Trust's Board of Governors, which would have been aware of the complaints made to it by the members of Cure the NHS (CURE).

18.116 In spite of the absence of concerns being expressed through student feedback, Professor Garner did not, and does not, consider that this means that the arrangements in place were ineffective, because there were a number of explanations for this:

- Students had not witnessed concerning behaviour, which is considered to be a possibility.
- Students had witnessed concerning behaviour, but had not recognised it as such, which is considered to be extremely unlikely.
- Students had witnessed such behaviour and recognised it as such but had not reported it; this is also considered to be unlikely.

18.117 Keele also seems to have placed considerable reliance on feedback from GMC inspections. At a GMC meeting on 15 March 2007, standards at the Trust were discussed and from this Professor Garner's overall impression from the GMC was that "students were receiving a good level of training at the Trust".[110] Yet in this report it was also stated that the visiting team had limited observation of teaching but were satisfied that staff and students were happy with the teaching structures at Stafford.[111]

18.118 Professor Garner explained to the Inquiry[112] that a review had been undertaken of the information the University had received from students over the relevant period, and none of the concerns uncovered by the HCC had been communicated. He accepted that the University would have wanted to know about them at the time. He could offer no explanation why the University had not become alert to any of them. This review was not in fact undertaken by the University until June 2011 in preparation for his giving evidence to the Inquiry. The 2011 review did not seek out the reasons why the Medical School had been unaware of issues surrounding the quality of care, or why students had not raised them or whether those reasons were relevant to the suitability of the Trust as a location for students.

107 Garner T107.140
108 Garner T107.138
109 Garner T107.116–7
110 Garner WS0000050360; AG/3 WS0000050396
111 AG/3 WS00000503896, para 27
112 Garner T107.141–142

18.119 Although Professor Garner emphasised that he was not Head of the Medical School, he would have expected to be aware of any specific earlier review had one occurred. Since he gave his oral evidence, he and the University have provided more detail than he was able to do earlier. They have stated that an earlier review was not carried out because it was considered such a review would have been unlikely to assist in distinguishing between the various possible reasons (see above) why student feedback had not raised concerns about the Trust. They were concerned with the impact of the fallout of the HCC report on their students and took appropriate action in that regard. They considered it better to take prospective action to improve the position for the future. The action taken has involved:

- A reduction in the number of students placed at the Trust, cancelling a previously planned increase;
- An increase in the monitoring of students at the Trust, involving the Director of Undergraduate Studies visiting students at the Trust monthly and proactively asking them if they had any concerns about patient care;
- Appointment of a Hospital Dean for the Trust and a student support officer to liaise with the School, mentor students at the Trust and detect concerns at the earliest opportunity;
- Introduction into the curriculum of a focus on patient safety;
- Steps to encourage the reporting of concerns including a formal written procedure, an annual road show on whistleblowing, and safeguarding training for students;
- Inclusion of a consideration of patient safety issues in quarterly meetings with the Trust, in the annual report, and in the quality assurance visit schedule.

18.120 The need for such action confirms that the previous system of oversight did not have a sufficient focus on patient safety and care standards issues. It is clear that the system was not effective to detect matters that were of concern for the fitness of the Trust as a location for medical education.

18.121 While the system in place in 2009 and before may have been consistent with standard practice, there was a lack of an urgent review into the reasons why the School was not aware earlier of the concerns, and what lessons it might learn for the future. This is a surprising omission indicative of an attitude that patient safety was not its concern, but someone else's, even after the HCC report. This impression was strengthened by the lack of detail Professor Garner was able to give in his oral evidence. It was also of concern that Professor Garner did not accept in his oral evidence to the Inquiry that students trained in an environment where poor standards were prevalent might learn to accept them as the norm.

MS HUGHES: It might be suggested that if poor quality care is endemic in an organisation, and it's not being addressed by the management, that undergraduate students who are lacking in experience may well simply accept it as the norm. Do you recognise that as a possibility as to why concerns in this case were not being fed back to you?

A. Do I ... ? No, I don't think I – I accept that. I think that medical students, indeed all healthcare students, are pretty bright individuals, actually, and I think that I would be very surprised if they were unable to recognise the – the substandard care and the bullying environment to which you have referred.[113]

18.122 He stated subsequently to the Inquiry that it was "reasonable" for the point to be made that students might learn to accept poor standards as the norm and contended that there was no evidence that students were in fact exposed to poor care. The lack of evidence one way or another is unsurprising given the absence of a retrospective review by the University.

18.123 Whatever concerns may have been raised by the lack of an immediate review and Professor Garner's oral evidence, the University has now demonstrated that it is more fully alive to the need to maintain a focus on patient safety issues and not to rely as exclusively on student feedback as it had done in the past. Students who lack experience of observing high standards of care cannot be expected always to pick up causes for concern in a poorly run organisation; they may believe what they are seeing is an acceptable norm. Therefore it is important that medical schools have means other than student feedback to satisfy themselves that locations in which they place students are fit for purpose.

GMC QABME monitoring and visits to Keele University

18.124 Before the publication of the HCC report, the School had been planning to increase the usage of the Trust to over 1,000 student weeks. In spite of the critical HCC report it continued to believe that the Trust could deliver good-quality learning for students. There was scant evidence offered to the Inquiry of any systematic process adopted by the University itself to monitor the quality of the environment into which it was sending its students.[114] It appeared to rely on feedback without seeking out evidence in this respect.

18.125 Having been accredited by the GMC in 2005, the Trust's position as a placement for students is assessed for revalidation every five years.[115] There were annual meetings between the GMC and School staff with quality assurance reported as being delivered to the relevant GMC committee.

2006

18.126 The GMC team visited the Keele Medical School as part of its review of the Manchester School in June 2006.[116] The team learned that clinical placements had been established at the Trust and these were described. The Trust was not visited, although the University Hospital of North

113 Garner T107.144
114 Garner T107.152–155
115 Garner WS0000050360, para 14
116 *QABME: Manchester Medical School, The University of Manchester Report for 2005/2006* (September 2006), www.gmc-uk.org/static/documents/content/Manchester_2006.pdf

Staffordshire was, in order for the team to view the teaching facilities. No adverse observations relevant to patient safety were recorded.[117]

2007

18.127 The GMC undertook four visits to the Medical School between February and June 2007, but only one of these included a visit to the Trust.[118] A team, consisting of a GMC team leader and support staff, visited the Trust on 15 March 2007. At that time there were 20 students at the Trust who were studying for the primary degree and had been placed there for an eight-week block. It was planned to increase this number to 30 students by 2009/10. The team was satisfied with the training they observed although they described it as "old fashioned" and "consultant based".[119] The visit did not include visiting wards or the A&E department.[120] The team considered that staff support for the students was currently adequate although they were concerned that more support would be required with the planned increase in student numbers.

18.128 The report to the GMC Education Committee identified a number of recommendations, including the need for the School to establish an explicit mechanism to engage with all NHS partners in primary and secondary care.[121]

2008

18.129 This issue was the focus of a visit to the School in 2008, but the Trust was not visited as it was perceived that there was no need to do so.[122] However, representatives of the Trust were seen.[123] The question of staffing was pursued by the GMC in 2008/09 and it considered that educational staffing levels were sufficient. The focus would have been on educational rather than general service staff.[124] The theme of engagement with NHS partners was identified as a continuing theme to watch. Concern was expressed about the lack of engagement of the chief executives, although the involvement of medical directors of acute trusts was welcomed.

2009

18.130 The first hint of serious concerns about the Trust came in an email sent by the GMC to the Keele Medical School on 6 March 2009. It had received information that the HCC report, which was about to be published, would be "challenging", and requested an analysis from Keele of how students might be affected.

117 *QABME: Manchester Medical School, The University of Manchester Report for 2005/2006* (September 2006), www.gmc-uk.org/static/documents/content/Manchester_2006.pdf
118 Dickson WS0000048820, para 76; ND/25 WS0000049641
119 AG/3 WS0000050396
120 Dickson WS0000048820, para 76
121 Dickson WS0000048821, para 77; ND/26 WS0000049656, para 17a
122 Dickson WS0000048821, para 78
123 ND/28 WS00049684
124 Dickson WS0000048822, para 79

18.131 According to Professor Garner, this was the first intimation the University had that there was cause for concern at the Trust.[125] Prior to that there had been no feedback from students suggesting cause for concern.[126] He would have expected students to report serious concerns about patient care as, in his experience, they are not backward in coming forward.

18.132 The reply from Professor Richard Hays, Chair of Medical Education and Head of School, was insouciant:

> *I personally am not sure that the problems there (mostly past?) have affected our students much at all. They had had relatively few students and I understand the feedback to be OK. However what we now face is a very difficult situation with staff morale at Mid Staffs. The challenge is to our expansion there.*[127]

18.133 By 17 March 2009 the tone had changed. Professor Hays asked the GMC for approval of plans to change arrangements temporarily so as to move certain modules away from the Trust given the concerns about continuity of arrangements with the new executive team and about governance structures.[128] However, it appears that the Medical School was caused no concern about the accuracy of its past positive view of the Trust as a training venue. In an email of 24 March Professor Hays said:

> *We have actually been very happy with our engagement with that Trust so far and our students have had good quality learning experiences there. We believe that the issues in the current public debate were in the past and have been resolved, but that this issue will drag on for a few months and may de-stabilise things a little. For example, we had an excellent relationship with the senior management and had agreement on increasing investment and teaching activity ... we suspect that expansion of teaching will not be the first priority of the new team ...*[129]

18.134 In a plan received by the GMC on 30 March, the School proposed placements for 1,142 student weeks at the Trust in 2010/11.[130] New measures of quality assurance were proposed which were to include:

- The use as before of student evaluations;
- A mid-placement visit from a member of the School to discuss the placement with students;

125 Garner WS0000050363, para 26
126 Garner WS0000050366, paras 37–39
127 Dickson WS0000048821, para 80; ND/29 WS0000049699
128 Dickson WS0000048822, para 82; ND/30 WS0000049702
129 ND/30 WS0000049703
130 ND/31 WS0000049706

- The use of a newly established reportable significant event system to enable students to report, in confidence, concerns about professional practice that they witnessed and for appropriate action on these to be taken;
- A weekly session run by the Director of Undergraduate Programmes for students to communicate concerns.

18.135 The GMC QABME team visited the School for quality assurance purposes on 22 January, 24 June and 13 July 2009, with a further documentary review in April. The team reported in November 2009.[131] Discussions were held with students, but it is unclear whether any visits were made to hospitals. The team was sufficiently satisfied to persuade it to make no recommendations for change. The report made no mention of the Trust or its difficulties.

18.136 It is remarkable, in the context of the appalling care and serious concerns uncovered by the HCC's investigation, that in a quality assurance report on medical training, some of which had been and would continue to be delivered at the relevant hospital, no express consideration was given by the QABME team in its report, or the GMC on receiving it, to the implications for the hospital as a training placement. It might be argued that future students had been safeguarded by the new quality assurance measures put in place, but that at least could have been recorded. However, there is no evidence that the failure of the system to have captured any concerns in the past had caused any concern, either at the Medical School or at the GMC. There is evidence of a degree of complacency in the immediate response of the School and the GMC to the HCC findings which suggests it gave inadequate significance to the risks to patients and the questions thereby raised as to the Trust's suitability as an educational setting. Such complacency runs counter to the professed priority accorded by the GMC to the protection of patients. While Mr Dickson, on behalf of the GMC, has expressed the belief that it was "extremely concerned" about the situation at the Trust, this was, as he accepts, not apparent from its communications at the time. Without such communication, and the leadership that would go with that, the GMC had not highlighted these issues.

18.137 Mr Dickson said that quality assurance reports are not about measuring the quality of care but he would have hoped that if a person carrying out the visit saw something of concern they would report it.[132] It might be thought that this was a statement of the obvious in a professional medical setting, but the attitude displayed in reaction to the HCC findings suggests that it might not be so obvious to busy and preoccupied academic visitors, however well intentioned. There is a need to reinforce their duties in this regard by explicit guidance and standards. As demonstrated above, the absence of reference to the wider aspects of patient safety in the GMC's education standards is undesirable and should be remedied.

131 Dickson WS0000048822, para 83; ND/32 WS0000049710
132 Dickson WS0000048823, para 85

18.138 Put shortly, training should not be permitted to take place in settings where the deficiencies of the type discovered at the Trust can occur.

PMETB monitoring of postgraduate training

Specialty visit for training in general internal medicine, 2005

18.139 A specialist team, provided by the Royal College of Physicians acting on behalf of PMETB, reviewed the Deanery over two days in respect of the renewal of its approval for the specialty programme in general internal medicine in 2005.[133] This review considered posts at 16 out of 31 LEPs including the Trust. A range of documentation was reviewed, and 70 SpRs (out of 250 in this specialty in the region), 21 college tutors, 36 consultants and 2 clinical directors were among those interviewed. It does not appear that any LEP was physically visited. The report, dated 22 December 2005, noted that some hospitals, including Stafford, were commended by trainees for the quality of supervision.[134] Other sites, which were named, were said to have issues including:

- Inconsistent consultant ward rounds;
- Little follow-up for patients seen by trainees;
- Isolated trainees due to staffing problems;
- Lack of clear structure of what trainees were supposed to do;
- Poor relationship between management and medical staff impacting on supervision of trainees;
- Trainees unaware of whom they should approach to discuss problems concerning acute receiving.

18.140 The approach illustrated by this report was similar to that adopted by some Royal Colleges when charged with the approval of specialty training before the inception of PMETB, but there had been considerable variation in practice and effectiveness.[135] PMETB sought to introduce a common system assessing programmes to common standards.

Deanery-wide visit, March 2007

18.141 A report was prepared by PMETB following a Deanery-wide cross-specialty visit in March 2007.[136] The team on this occasion consisted of nine members from various disciplines.

18.142 They visited the Deanery and two hospitals, but not the Trust. Concerns were raised about the safety of trainees at one site (a mental health hospital), and about trainees not reporting critical incidents because nothing seemed to be done about them. It was critical of the

133 Streets T107.10; PS/9 WS0000046802
134 PB/9 WS0000046813
135 Streets T107.17–18
136 PS/11 WS0000046862

Deanery for its lack of effective or robust quality management and recommended a more proactive approach.[137] It found that trainees had not received the PMETB national survey, and there was no systematic review and evaluation of such feedback as was received from trainers or trainees. Such feedback is a vital component of the contribution the system for training regulation and oversight can make to patient safety. There was also criticism of the lack of an effective Deanery anti-bullying policy, and of bullying between specialties on one site which was said to compromise patient safety.

Follow-up of report

18.143 After considering the Deanery's response to the report PMETB endorsed it and required action to be taken.[138] Conditions were set for the Deanery which included the development of a complete proactive system for its quality management processes and active engagement with the colleges. It was also required to review existing college visit reports to ensure implementation of recommendations. Other conditions referred to the bullying and safety issues.[139]

18.144 The Deanery reported back to PMETB on its action in relation to the report's recommendations in October 2007.[140] In July 2008, PMETB chased a response in relation to certain recommendations.[141] Finally, in August 2008, PMETB wrote to confirm its acceptance that the conditions had been fulfilled and full approval was granted to the Deanery.[142]

Conclusion

18.145 The initial specialty visit considered above, undertaken by the Royal College of Physicians on behalf of PMETB, illustrates some of the strengths and weaknesses of the system which had preceded it. Clearly, interviewed senior trainees could bring to light issues of concern about training, and in particular any which might have an impact on patient safety. Senior members of the college could be expected to understand readily the implications of what they were being told. The 2005 report contained some very specific and clearly expressed concerns. However, the approach is likely to have suffered from an absence of visits to actual training sites and observation of the circumstances in which trainees had to work, and the inevitably limited number of trainees who could be seen in a two-day period. Additionally there was a lack of consistency between different colleges and teams in how they conducted this sort of visit, making the process rather variable in its effectiveness.

18.146 The PMETB system of review commenced after that also illustrates the type of concerns that could be revealed by Deanery inspections, but of course they could only be effective in

137 Hughes WS0000062165, para 33
138 PS/11 WS0000046891
139 PS/8 WS0000046788
140 PS/11 WS0000046911
141 PS/11 WS0000046914
142 PS/11 WS0000046915

relation to the trusts whose trainees were seen. Where it was found that the Deaneries' own quality management processes were non-existent, or not functioning effectively, some steps should have been taken to obtain assurance in relation to all providers. Assurances were accepted that the Deanery had set up a quality management system covering all providers, including the development of a plan to raise awareness of trainees and trainers about bullying issues.[143] However, the approach seems to have been one of reacting to reported deviations from standards rather than much proactive searching for such deficiencies.

PMETB national surveys

18.147 PMETB had a programme of national surveys for trainees, starting in 2006. Response rates started at about 60%, but subsequently increased to around 85%.[144] The first survey was focused on PMETB's generic standards, and the later ones added specialty-specific questions. Mr Streets thought they did not determine whether standards were being met but were useful in providing a snapshot of the perceptions of those involved in training.[145]

18.148 Surveys of trainers were also introduced,[146] but these had a lower response rate and therefore were less useful.

2006

18.149 In 2006 the Trust was an outlier in positive responses and not in any negative response. The areas looked at were somewhat limited. It appears that only three areas of activity were looked at: anaesthetics; medicine; and obstetrics and gynaecology.[147]

18.150 This survey was received by the Deanery in 2007. Dr Elizabeth Hughes, at the time Acting Associate Dean for Quality Assurance, said that this meant that the Trust was not at "the forefront of minds at the Deanery going into 2008".[148]

2007 to 2008

18.151 In the survey conducted in December 2007[149] a wider range of activities was covered, now embracing six specialties. The Trust was a negative outlier in the areas of work intensity and induction in emergency medicine and "other learning opportunities" in surgery. The results of this survey were not available to the Deanery until May 2008.

143 PS/11 WS0000046912
144 Dickson WS0000048829, para 102
145 Streets WS0000046498, para 52
146 Streets WS0000046499, para 56
147 ND/38 WS0000049821
148 Hughes WS0000062174, para 73
149 EH/16 WS0000062513

18.152 Dr Hughes, by this time joint Postgraduate Medical Dean (with Professor Stephen Field), felt that the results were "unremarkable".[150]

18.153 However, the results were considered differently by PMETB. It gave an "amber" risk rating to the Trust in the areas of Patient Safety and Workforce Issues/Education and Training in November 2008.[151] An amber rating meant that there had been areas of concern to PMETB, but that they had been addressed. Such ratings were not part of PMETB's published methodology but were used as a means of communicating assessments to other agencies.[152] As a result PMETB submitted its rating to a risk summit in November 2008 relating to the WMSHA, although no PMETB representative attended that particular meeting. The meeting considered issues about a large number of organisations. It was attended by the HCC. It appears that the HCC investigation was referred to at the meeting. Mention of it appears in a note produced to the Inquiry by Dr Andrea Gordon.[153] It appears that the opportunity was lost to draw the attention of PMETB specifically to the HCC's ongoing investigation of the Trust as no representative of PMETB happened to be present. According to Mr Streets, it only became aware of this very shortly before the publication of the HCC report.[154] He later clarified that the investigation had been mentioned in the HCC's spreadsheet summarising the ratings from the risk summit, but this was not logged in PMETB's system until shortly before the HCC's report was published.[155] The Health and Safety Executive was represented at this meeting and its inspector, Mr Brookes, asserted that it also was left unaware of the investigation at this time: an elliptical reference to a "major report into critical pathways" had not been understood at the time.[156] To the extent that the investigation was referred to at the risk summit, it appears that the significance of this was not communicated so as to result in it being fully understood or appreciated by all the organisations involved.

2009

18.154 On this occasion the Trust was a negative outlier in:

- Overall satisfaction in general surgery;
- Workload in haematology;
- Handover in haematology, and obstetrics;
- Learning opportunities in haematology;
- Feedback in surgery.

150 Hughes WS0000062174, para 74
151 Streets T102.66–68; Streets WS0000046502, para 66; Dickson T105.101–103
152 Dickson T105.101
153 Gordon WS175 WS0000024130; AG/80 WS000002848
154 Streets T102.69–71
155 PMETB00000000003, Letter to the Inquiry from Field Fisher Waterhouse LLP with update on two matters Mr Streets said he would follow up from his oral evidence (7 July 2011)
156 Brookes WS0000050832, para 84; Brookes T109.92, 98–99

18.155 The Trust was in the higher, positive centiles for educational supervision, and for work intensity in all four disciplines recorded (which did not include emergency medicine or medicine).

Conclusion

18.156 These reviews surveys, while potentially useful and worthy of development, suffered a number of problems which hindered useful interpretation. The numbers of respondents in any area could be quite small. As can be seen, there were wide variations in results from year to year, and therefore no suggestion of a recurrent theme.[157]

18.157 Where the numbers of respondents were so small that there was a risk they could be identified, the results were omitted from reports. This may have meant that single expressions that raised serious concerns were missed, although the intention was that these would be taken up individually.[158]

18.158 There was a concern about the time lag from when surveys were conducted to when the results were available. It could take four or five months for data to be collected and analysed.

18.159 There is a demonstrable need to develop surveys of students and trainees as they are a valuable source of information about the standards of the service delivered by providers of healthcare. They have the advantage of being new to an establishment, less affected by any adverse culture, and, with appropriate support, less likely to be inhibited by career considerations. On the other hand, it would be wrong to place too much reliance on this source of information for the reasons advanced above.

Deanery review processes

18.160 These were conducted in accordance with the Deanery's Postgraduate Training, Ongoing Quality Review and Enhancement Framework.[159] This provided for four types of review, to be conducted on a standardised basis:

i. Scheduled LEP reviews;
ii. Exceptional LEP reviews;
iii. Full programme reviews;
iv. Deanery reviews.

157 Dickson WS0000048829, para 103
158 Streets WS0000046498, paras 54–55; Dickson T105.64
159 EH/7 WS0000062347

18.161 Such reviews could be undertaken on one of four levels, ranging from a desktop review to a full GMC investigation, depending on the degree of concern raised and the response to such concerns.[160]

Self-assessment by the Trust required by the Deanery

18.162 The Inquiry was shown three annual self-assessments by the Trust in 2008, 2009 and 2010.[161] The forms for these were part of a continuing and evolutionary development of quality management processes, and the 2008 form was the first one deployed.[162] The form was constructed to allow LEPs to set out against each PMETB domain and standard examples of the evidence relied on by the Trust, a list of evidence, areas of achievement and areas of concern.

2008

18.163 In the 2008 return the only areas of concern referred to were in relation to "take out" (TTO) prescribing, and IT access for trainees. Under the domain of patient safety and the requirement for adequate supervision for trainees, the items of evidence listed as relied on were Job Evaluation Survey Tool (JEST) results, PMETB 2006 trainer results, and the staff rota.

2009

18.164 The next return was submitted in August 2009. Separate reports were made for:

- The foundation programme: three issues had been identified since the last review – work load for FY2 doctors in medicine, an increased requirement for skills rooms, and increased access to IT facilities;
- Paediatrics: no issues were identified;
- Surgery: no issues were identified;
- Obstetrics and gynaecology: no issues identified;
- Anaesthetics: no issues identified.

18.165 It is quite remarkable that such reassuring assessments could be offered in the immediate aftermath of the HCC report. Indeed, these returns give the appearance of not having been fully completed and of being very superficial. While the Inquiry has not undertaken detailed examination of underlying documentation, these returns would not justify any confidence in the level of compliance with standards actually attained.

160 Hughes T114.20–21
161 EH/8 WS0000062403
162 Hughes T114.22

2010

18.166 In 2010 a different format of return was required. This gave details of the number of trainees at the Trust. There was also a list of the actions required by specialty visiting teams and of progress made. In marked contrast to the previous returns, a long list of required actions appeared, including detailed improvements for paediatric care in A&E, relationships between A&E and surgery, surgical workload, and A&E rotas. Under the domain of patient safety, these included:

- *"Difficult relationship between surgery and emergency medicine department";*
- *"Confusion over reporting and feedback of adverse incidents" in surgery;*
- *In paediatrics, "concern over blue light non-elective paediatric pathway".*[163]

Conclusion

18.167 Dr Hughes agreed the earlier returns were not satisfactorily completed but pointed out that this method was under development. She said that the Deanery had experienced some difficulty in getting trusts to complete these returns thoroughly or to return them at all. In the early stages, the focus was more on getting trusts used to completing the forms. She also agreed this sort of information was not sufficient and that there was a need for triangulation, which, she says, now happens. Evidence is taken from the GMC and JEST surveys, other forms of trainee feedback, visits, the quality observatory, CQC alerts, SUIs and so on, all of which is fed into the Deanery's database.[164] Therefore the system has developed a long way from where it was in 2008. The Deanery was complimented on its strengths in this area in the PMETB visit report of October 2009.[165]

18.168 The inadequacy of self-assessments and self-declarations as a form of external monitoring is commented on elsewhere in this report. Until the 2010 return, the forms returned by the Trust give the impression of an LEP at which there were no serious concerns, even while such concerns were mounting to the knowledge of the Deanery. While such a process in the training context could be helpful in contributing to the LEPs' governance, the type of return used in 2008 and 2009 was useless to the Deanery if it was not going to be taken seriously by LEPs whose reluctance to complete yet another bureaucratic form was entirely predictable, and unless the information supplied was confirmed from other sources. The 2010 edition is certainly an advance on its predecessors, but given its reliance on summarising the reports and recommendations of external groups, there may be better ways for a Deanery to collect this sort of information. Where, for example, peer reviews take place, it would be better for the reviewing body to share its relevant findings, recommendations and follow-up with the Deaneries, thus avoiding duplication and providing a degree of independent assurance absent from a self-assessment. From the evidence of Dr Hughes, this approach is now being taken.

163 EH/8 WS0000062456
164 Hughes T114.25–6
165 WS0000062192; WS0000062713

Visits to the Trust

18.169 Deanery visits took place at the Trust on a number of occasions.[166]

December 2005

18.170 A scheduled visit took place on 8 December 2005.[167] Concerns were raised about the induction of trainees, inappropriate tasks being undertaken by trainees, monitoring of workload and the number of wards covered by some FY1 doctors.[168] In response to the concern about induction, the Trust pointed out that the visit occurred when trainees had literally just been installed in post and before inductions could reasonably have been completed. The letter containing this response,[169] which rejected a number of other criticisms, from the Head of Medical Education to the Dean, Professor Field, was positively hostile and very critical of what were said to be inaccuracies in the report:

> *Overall, I am very disappointed with the conduct and quality of the visit by the Deanery team on this occasion. Investigation of the evidence made available to the team was cursory. No allowance seems to have been made for the fact that we are embarking upon new foundation posts which although this hospital was piloting from August 2004, the programmes only formally started in August 2005. The team seems to believe they have to be ever more prescriptive to the point that even for an educational enthusiast like myself, their demands are insensitive and unreasonable based largely on information which is blatantly untrue ... Your team has been ridiculed by many, and this weakens the Deanery's own position. This is not helpful.*[170]

18.171 The Deanery responded with a visit from Dr Marc Whitehouse, the Director of Hospital and Specialist Education, on 7 March 2006, following which he wrote to the Trust on 27 March,[171] accepting some of the criticisms and explanations. A follow-up visit occurred in September 2006, the outcome of which was understood to be satisfactory.[172]

Visits between 2005 and 2008

18.172 Between 2005 and 2008 it is believed that two visits were made to the Trust on behalf of the Deanery by Mr Obhrai or his predecessor Colin Campbell in their capacity as Associate Dean for the foundation programme. No record is now available of these visits or their outcome.[173]

166 EH/9 WS0000062463
167 EH/11 WS0000062469
168 EH/11 WS0000062473
169 EH/13 WS0000062483
170 EH/13 WS0000062490
171 EH/14 WS0000062493
172 Hughes WS0000062174, para 72
173 Hughes WS0000062174, para 72; Obhrai T55.51

May 2008

18.173 The Deanery conducted a scheduled review of the Trust in May 2008.[174] It was conducted by a team including Mr Manjit Obhrai, the Associate Dean of the Foundation School, a clinical tutor from another acute hospital, and a professor from Keele University Medical School. The team met the clinical directors, educational supervisors, and the majority of the FY1 and FY2 trainees. The report of this visit recorded that the domain of patient safety was not covered. Dr Hughes, by now the Dean, suggested[175] that the intention was that the information recorded in other sections of the report would feed into the patient safety section. This does not appear to have happened. In any event, she did not consider on reading the report that the issues described raised patient safety concerns. The review highlighted issues about bullying from staff and poor consultant cover in A&E (although middle grade doctors were said to be very supportive).[176] Workload for FY1 trainees was described as "high" in colorectal surgery and "very busy" in medicine.[177] FY2 trainees described "too much paperwork, one doctor covering 40 patients" in trauma and orthopaedics and a "high level of work" in A&E, "although it is very challenging and a good learning environment". There was said to be some pressure to discharge patients when a decision had not already been made, especially at weekends:

> *Trainees stated that they are not sufficiently knowledgeable of the patient condition to make the decision to discharge. There was some issue regarding the aggressive behaviour of bed management and trainees often felt intimidated.*[178]

18.174 In the Medical Directorate, trainees alleged that they were unaware of the bullying and harassment or whistleblowing policy and no one knew how to escalate issues.[179] The recommendations listed included:

- *Trainees were not aware of policies for handling bullying and harassment or whistleblowing;*
- *There was one example of a potential bullying issue and the inappropriate pressure from non-medical staff in their efforts to meet the 48 [sic] hour waiting time in A&E;*[180]
- *There appeared to be some resistance to training by some members of the faculty;*
- *A mechanism for feedback appeared to be weak …;*
- *There was some pressure on the part of the non-medical staff to encourage trainees to miss training sessions;*
- *There was some pressure applied to trainees to under-report the number of hours worked".*[181]

174 Hughes WS0000062174, para 74; EH/17 WS0000062529; Hughes T114.53–63
175 Hughes WS0000062176, para 81
176 EH/17 WS0000062536
177 EH/17 WS000006236–37
178 EH/17 WS0000062537
179 EH/17 WS0000062538
180 It is presumed that this was intended to refer to the four-hour waiting time target.
181 EH/17 WS0000062539–40

18.175 In spite of these concerns, the overall outcome of the review was said to be "satisfactory" and it was concluded that the foundation school could address the issues identified. No formal action plan was required but the Trust was asked to provide documentation describing improvements made as a result of the review.

18.176 Dr Hughes, the Dean, told the Inquiry that this was one of the first reviews using the new documentation and that whether the outcome was "satisfactory" was a matter for the inspectors. She interpreted this to mean that it was thought that the issues found could be addressed by the School without referral to her. As the outcome of the review was said to be satisfactory, she would not have had cause to review the report personally. To have done so, she contended, would have involved her in undue workload.[182] On reviewing the report for the Inquiry, Dr Hughes did not consider that it should have given cause for concern in any event:

- She thought that the work level in A&E reported was a positive indication of a good training environment;[183]
- Dr Hughes considered that lack of awareness of bullying and similar policies was common.[184]

18.177 Dr Hughes told the Inquiry that the experience at Mid Staffordshire NHS Foundation Trust has led to a heightened degree of sensitivity to concerns detected and described the measures now taken.[185] Accordingly, in its annual report to the GMC for 2010, the Deanery stated that it had carried out "a proportionately greater number of reviews" of the Trust. The first of these, an exceptional review of paediatrics, did not take place until 4 May 2010. In total, the Deanery carried out 10 reviews (both scheduled and exceptional) between May 2010 and May 2011, with a further review still to be scheduled at the point the report was submitted to the GMC on 30 December 2010.[186]

Conclusion

18.178 With the benefit of hindsight, this review did raise issues which were entirely consistent with the findings of serious deficiencies at the Trust, findings which were being made almost simultaneously by the HCC. However, it seems, from the evidence of Dr Hughes, that a conclusion by the visiting team, that the overall outcome of the inspection was "satisfactory" was entirely in accord with the expectations of the system under which they were operating. That is, if any concerns identified could be addressed locally there was no need for escalating them to the Deanery. This meant that the signs recorded by the team were not picked up and pursued by the Deanery with a view to the important domain of patient safety. Probably

182 Hughes WS0000062175, para 77; Hughes T114.77–79
183 Hughes WS0000062176, para 83
184 Hughes WS0000062176, paras 82–85
185 Hughes T114.79
186 Hughes EH/55 WS0000062815

as a result of this, the wider implications identified by the HCC were not detected by the visiting team.

18.179 While reports and complaints from trainees must be reviewed with a degree of caution because of their lack of experience, this report does at least illustrate the value of the information capable of being obtained in relation to patient safety, and the importance of highlighting such information and bearing in mind its relevance to the protection of patients.

18.180 Dr Hughes has assured the Inquiry that the approach has been changed since the HCC investigation to ensure a heightened degree of sensitivity. Even at the time, it is fair to note, neither she personally nor the Deanery generally were complacent about bullying: induction packs and their website contained information about this issue, and workshops on it were offered annually.

18.181 The weakness of the system followed then was not that issues of concern, such as bullying, were ignored – they were not. It was that no overall consideration was automatically given as to whether such issues implied concern for patient safety. Looked at from such a perspective, and learning the lessons available with the benefit of hindsight, this report should not have been treated as indicating a satisfactory outcome, but rather as showing the need for a more in-depth look at the hospital and its suitability as a training establishment. Clearly, there are resource issues and a need for proportionality in response to the concerns raised, but the priority to be given to ensuring patient safety and to avoiding exposing trainees to the risks of unsafe practice needs to be paramount. If the mechanisms for supervision of training are incapable of undertaking sufficient monitoring of safety issues, then it must be obligatory for the responsible bodies to pass on information relevant to safety to the responsible regulator. However, in this case, any deficiency attributable to the attitude to this report was short-lived because very soon afterwards Dr Turner drew his serious concerns about A&E to the Deanery's attention.

Concerns raised by Dr Turner, May to June 2008

18.182 Shortly after the May 2008 review, the Dean was informed of the serious concerns raised by Dr Turner about A&E.[187] What happened has been fully described in *Chapter 1: Warning signs*. Dr Hughes asked the Head of School to get Dr Turner to complete a JEST survey form, which he did.[188] JEST was unique to the West Midlands and was rolled out in 2008 and 2009. Data from this was available within two or three weeks and the survey would normally receive maximal return.[189]

187 Hughes WS0000062177, para 86; EH/20 WS0000062550; PS/13 WS0000046946; Streets WS0000046503, para 68
188 Hughes WS0000062177, para 86; EH/19 WS0000062547
189 Hughes T114.33–35

18.183 This was the very first time in a specialty that a trainee had been asked to fill in one of these forms.[190] Dr Turner's response raised concerns about patient safety, supervision, appraisal, medical cover, workload and audit. He would "categorically" not have recommended the post to friends.

18.184 When asked about the obvious discrepancy between the Deanery review report and Dr Turner's complaints, which all arose in the same month, Dr Hughes accepted that she would have expected the trainee's concerns to have been mirrored in the review. She speculated that it may have been the case that foundation year trainees were receiving appropriate supervision from Dr Turner, but that this could have placed excessive pressure on him (the difference arising through a difference of experience between trainees). More junior trainees would have been supervised by Dr Turner.[191] In her interview as part of the HCC investigation she had suggested that:

> *Trainees were reluctant to come out and criticise training, and this is a universal problem because often trainees are not convinced that the survey is anonymous and they worry it will have an impact on their future career.*[192]

18.185 Dr Hughes communicated this information to Peter Blythin at the SHA, informing him that the placement was inappropriate and that the trainees should be removed.[193] The Specialty Training Committee (STC) Chair for Emergency Medicine and the Head of School had requested that trainees be withdrawn and placed elsewhere.[194] However, as she explained in her oral evidence, it was difficult to remove a trainee, in part because of the consequences for the running of the A&E department[195] and in part because of the consequences for the trainee.[196] In the end, Dr Turner was not removed. Dr Hughes appears to have obtained reassurance from her subsequent knowledge that the HCC was undertaking an investigation. A review by Heart of England NHS Trust was also under way, and a further consultant had been brought in from University Hospitals North Staffordshire (UHNS).[197]

18.186 Dr Hughes raised the concerns with Dr Val Suarez, Trust Medical Director, and confirmed this in an email on 25 June 2008, copied to Mr Peter Blythin and Dr Rashmi Shukla.[198] Dr Suarez responded with an action plan[199] which included the proposed recruitment of four whole-time equivalent (WTE) consultants in emergency medicine and nine WTE middle grade

190 Hughes T114.37–38
191 Hughes WS0000062181, para 100
192 EH/32 WS0000062612
193 Blythin WS0000019679, para 153; PB/30 WS0000020070
194 EH/21 WS0000062553
195 Hughes T114.83
196 Hughes T114.175
197 Hughes T114.85
198 EH/21 WS0000046949
199 EH/22 WS0000062555

appointments. Dr Hughes forwarded the plan to Mr Blythin at the SHA. She received regular updates from the Trust about staffing levels and action taken.[200]

18.187 Working with a consultant from another trust who happened to be employed at the Trust at the time, Dr Hughes considered that the action plan was, in principle, satisfactory but wanted to ensure its effective implementation by rigorous follow-up. For instance, having individuals responsible named, and a rota produced for review.[201] She made no contact directly with the HCC or Monitor over these issues, because her line management was with the SHA, which she assumed would undertake any necessary liaison with the regulators.[202]

18.188 It was only during discussions with Mr Blythin and Dr Shukla at the SHA about this matter that Dr Hughes became aware of the HCC investigation.[203]

18.189 Dr Hughes did not communicate directly with the HCC about the concerns raised by Dr Turner. She told the Inquiry that she understood from Dr Shukla and Mr Blythin that the HCC was examining the Trust's A&E and had identified the same concerns. Her impression was that Dr Shukla and Mr Blythin were liaising with the HCC on these issues.[204] It does not appear from her evidence that she actually discussed with these SHA officers whether they had forwarded information about Dr Turner's concerns to the regulators.

18.190 Dr Hughes asserted that, until interviewed by the Inquiry, she had not seen the HCC letter of 23 May 2008 outlining the HCC's serious concerns about the Trust's A&E.[205] On reading the letter, she agreed that it contained matters absolutely central to her work.[206] Mr Blythin's evidence was that the letter had been shared with Dr Hughes, along with correspondence from the PCT.[207] She denied this, telling the Inquiry that she had not been shown the letter or told about it by Mr Blythin or Dr Shukla, although, as it happened, she considered that the concerns expressed in it mirrored those which she was aware of through the Deanery's quality management process.[208]

18.191 Dr Hughes was interviewed by the HCC on 22 October 2008 in the course of their investigation. The HCC's note of the interview[209] recorded that Dr Hughes was asked about the May letter. She had stated that it had not been passed to the Deanery then, and that she had not been aware of it until she had raised Dr Turner's concerns with Mr Blythin and Dr Shukla. In her evidence to the Inquiry she denied she had said that, although she agreed the letter

200 Hughes WS0000062182–183, paras 103–109; PS/16 WS0000046954
201 Hughes WS0000062181–182, paras 101–102; Hughes T114.89–90
202 Hughes WS0000062182, 103
203 Hughes T114.49–50
204 Hughes T114.88
205 Hughes WS0000062178–180, para 89 and 97; EH/18 WS0000062542; Hughes T114.51–53
206 Hughes T114.51
207 Blythin T70.76–77
208 Hughes WS0000062178, para 89
209 EH/32 WS0000062612

had been mentioned.[210] Subsequently, an unapproved transcript of her interview came to light in which she was recorded as saying that she had not seen the letter. The note does not purport to record Dr Hughes as saying she had been told about it by Mr Blythin or Dr Shukla.[211]

18.192 Dr Hughes had a number of issues with the accuracy of the HCC's notes of the interview. As the HCC did not seek any agreement with interviewees as to the accuracy of interview notes, it would not be fair, in relation to an issue such as this, to reject her own recollection in reliance on them. However, the letter was undoubtedly copied at the time to the SHA. It is also common ground that Dr Hughes discussed concerns about A&E with Mr Blythin and Dr Shukla in a meeting at which she was told of the HCC investigation. On this evidence, taking full account of the difficulties in memory, it is probable that the letter and the concerns it raised were mentioned to, or to use Mr Blythin's term "shared with", Dr Hughes when she informed Mr Blythin and Dr Shukla of Dr Turner's concerns, but she was neither offered, nor asked for, a copy. Bearing in mind the importance of the concerns raised by the HCC in relation to the suitability of A&E as a training placement, this demonstrates a lack of focused thought being applied to the relationship between the supervision of training and patient safety issues. Dr Hughes should have asked to see the letter, and should have considered its implications in relation to training, rather than to assume that the concerns that she was already aware of covered the same ground.

Conclusion

18.193 When Dr Turner raised his concerns, it is fair to say that Dr Hughes organised a degree of rigorous supervision of the Trust's efforts to remedy the dreadful situation in A&E, although, in addition to her contact with the Medical Director, it might have been prudent to communicate directly with the Trust's Chief Executive, given the significance of what Dr Turner had to say.

18.194 She communicated appropriately with the SHA as her line manager, but it is striking that, in spite of belatedly becoming aware of the HCC investigation and simultaneously of safety issues at the Trust, she took no personal steps to liaise with either of the regulators and acted on an unconfirmed assumption that others at the SHA were doing so.

18.195 It is an indication of the low importance given to concerns raised in connection with the Trust that no one at the SHA thought to ensure that the Deanery had a copy of the HCC May letter.

210 Hughes WS0000062186, para 123; Hughes T114.53
211 EH/59 WS0000077890

Annual Deanery report, 2007/08

18.196 The West Midlands Deanery produced an annual report to PMETB for the year August 2007 to 2008.[212] It was produced in December 2008 in the form of an "exception" report. In other words, it purported to describe issues of concern requiring attention, rather than providing a general description of Deanery activity. No location is expressly mentioned in the report.

18.197 The report made no explicit reference to any concerns emanating from the Trust, even inferentially. By December the acting Dean, Dr Hughes, had been interviewed by the HCC and therefore was fully aware of the investigation. However, this report is designed to address a year ending before then. What is less easy to understand is the absence from the report of a reference to the concerns raised by Dr Turner about A&E in June. Dr Hughes had personally received a copy of his completed JEST form in that month and had taken the matter up with both the Trust and the SHA.[213]

18.198 Dr Hughes told the Inquiry she believed she was required to keep confidential the interview with the HCC and was assured that the HCC would share information with PMETB. She had assumed that the HCC would inform PMETB directly, and that inclusion of this information in a document which would be published was to be avoided.[214] She was unable to provide a satisfactory explanation about why she thought this prevented her including in the report information she obtained independently of the HCC and which she would otherwise have felt necessary to communicate to them.[215] The passage in the document provided by the HCC to interviewees does not deal with any restriction on interviewees' disclosure of information, but was addressed to assuring informants that in general the HCC would not identify sources of information.[216] Dr Heather Wood told the Inquiry she did not recollect any such conversation and did not believe she would have discouraged any other regulator from taking any action they believed necessary.[217] Dr Hughes did not attempt to communicate her knowledge confidentially to PMETB. When she realised that the HCC report would not be published by the time she had to submit the Deanery report, she did not seek clarification from the HCC about what she should do.[218]

18.199 Mr Dickson, Chief Executive of the GMC (although not at the time) thought that Dr Hughes should in any event have informed both PMETB and the GMC of the investigation as a matter of duty, regardless of any requirements she understood the HCC to be seeking to impose. [219] Paul Streets, then Chief Executive of PMETB, also told the Inquiry that he would have expected

212 Streets WS0000046503, paras 67–68; PS/12 WS0000046917; Dickson WS0000048831, para 108; ND/41 WS0000049865
213 For a full description see Chapter 1: Warning signs
214 Hughes T114.90–96; Hughes WS0000062188, para 130
215 Hughes T114.91–92; Hughes T114.93–95
216 PCT00140003827–8, *Healthcare Commission Investigation Into Mid Staffordshire NHS Trust: Notes for people being interviewed by the Healthcare Commission's Investigation Team*, p2 (needs putting on website); Hughes T114.96–97
217 Wood (fourth statement) WS0000074568–9, para 30
218 Hughes T114.99
219 Dickson T105.77

to have been told of the HCC investigation, but also expressed his understanding that she had been told not to disseminate that information.[220]

18.200 Mr Streets also told the Inquiry that he would not necessarily have expected to be told of the concerns raised by Dr Turner if, as it now appeared to him to be the case, the Trust had been approached and appeared to be taking the required action. He also pointed to the pattern of trainee responses from the Trust which suggested that there was "very good training" being provided there.[221]

18.201 The Inquiry is satisfied that Dr Hughes was not trying to mislead the Inquiry about what she was required to do by the HCC, and prepared to accept that she honestly misunderstood the position. However honest, to have come to that conclusion was a serious misjudgement with no logical foundation. She was in possession of highly concerning information about the Trust which had come to her from a source entirely independent of the HCC investigation. On her own account it was of sufficient gravity for her to have reminded the Trust of the powers to remove trainees. She had raised the issue with Mr Blythin at the SHA. Therefore there was no basis on which it could be said that the information in her possession was confidential to the HCC. If the HCC had really required the undertaking Dr Hughes has described, it would have been in excess of its powers. Dr Hughes failed to give sufficient weight to the interests of patients and the public in considering whether and how to make the training regulator aware of serious patient safety concerns. While Paul Streets in his evidence raised similar points as potentially justifying an omission to report this information, he was of course only addressing the question in retrospect and the fact remains that Dr Hughes possessed information of serious matters of which she should have made the regulator aware.

18.202 The result of the report not mentioning the Trust was an approval for the Deanery by PMETB, which remained in ignorance of a serious situation which should have led it to consider whether conditions should have been attached. As a result, no conditions relating to that serious situation were imposed.[222]

18.203 Even more surprisingly, Dr Hughes told the Inquiry that even if she had not believed she was bound by confidentiality not to inform PMETB of the developments at the Trust, she would not have done so in advance of submitting the annual report.[223] Her justification for that hypothetical position was that quality management was delegated to the Deanery and issues would be escalated to PMETB only if they could not be resolved. It cannot be right that, when a matter as serious as that reported by Dr Turner comes to light, the responsible regulator is left in the dark about it until an annual report arrives. It is deprived of the opportunity to undertake risk-based action and to assist and advise the Deanery and others.

220 Streets T107.86
221 Streets T07.80–1; Streets WS0000046503, para 68
222 EH/37 WS0000062661; Hughes T114.100
223 Hughes T114.101–102

18.204 Advice from the Inquiry's assessors is that the GMC still has no specific thresholds on what has to be reported in an annual report and that this is therefore left to the judgement of the Deanery.

Awareness of issues of concern

Royal College of Surgeons report, 2007

18.205 The Royal College of Surgeons (RCS) peer review report of 2007 labelling the surgical division as "dysfunctional" was not made known to the Deanery or PMETB.[224] The concerns raised in the report had obvious implications for the acceptability of training, in particular under the domain of patient safety.[225] Mr Streets, although not even aware of the existence of the invited review mechanism at the time, would have expected this to emerge in the annual specialty report, or in information given to the Deanery.

Staff shortages

18.206 Dr Hughes appears to have been aware for some time that the Trust's A&E was short-staffed. While she disputed the accuracy of the HCC's note of what she said in her interview with their team, she told the Inquiry that: "The problem of recruiting to this level had been in existence for some months and for a long time they only had one consultant."[226]

18.207 Dr Hughes agreed that staff shortages of the sort found by the HCC were central to her work in overseeing training provision.[227] Although the Deanery was seriously disadvantaged by not being sent a copy of the HCC letter of 23 May 2008, for the reasons explored above it was provided by the May 2008 review with sufficient hints that there was cause for concern and for a more detailed investigation even before Dr Turner made his complaint. One factor that may have inhibited the visiting team, and Dr Hughes (to the extent that she read its report at the time), as it inhibited others when faced with concerns, was that the Trust was not on its own in having an under-staffed A&E department.[228] While Dr Hughes agreed that this in itself did not remove potential concerns about patient safety, there is a sense of habituation to this sort of problem which desensitises even conscientious professionals and diminishes their level of concern. Dr Hughes sought to assure the Inquiry that this experience had resulted in the Deanery becoming much more sensitive to the patient safety implications of concerns raised in reviews, with more being demanded by way of structured action plans, deadlines and follow-up visits.[229]

224 Streets T107.33–34
225 Streets T107.35
226 Hughes WS0000062186, para 122
227 Hughes T114.51
228 Hughes T114.67
229 Hughes T114.79–80

The Healthcare Commission investigation

18.208 The GMC became aware of the HCC investigation by chance because of cross-membership between the HCC board and the GMC QABME team visiting Keele in April 2008.[230] However, the gravity of the concerns being uncovered does not appear to have been adequately communicated or understood until very shortly before the publication of the HCC report.[231] As late as the day before the report was published, an internal email between two officials dealing with education quality discussed changes to the curriculum and the possible need to defer use of the Trust site until governance arrangements had been clarified. In this email the view was communicated that "the situation" (ie the impending publication of the HCC report) was "a good test of their ability to respond to an external problem".[232]

18.209 The Deanery became aware of the investigation in June 2008 and the position taken by Dr Hughes is considered above. PMETB remained unaware of the investigation until 2009.[233] However, the HCC seems largely to have relied on the SHA communicating information about the investigation to the Deanery.

18.210 Steps have been taken to ensure that all properly interested regulators are kept informed of this type of development via risk summits and memoranda of understanding. The Health and Social Care Act 2012 contains provisions imposing a duty to cooperate in the exercise of their functions between the CQC, Monitor and various specified bodies, but, subject to inclusion in any statutory regulation, training regulators, with the exception of Health Education England, have not been included.[234]

18.211 The lack of reaction on the part of the GMC, with its admittedly limited understanding of the implications of the investigation, gives cause to question whether earlier knowledge would have prompted any more urgent action by any of these bodies, but at least proper information would have made it much more likely that there would have been some reaction. It is to be hoped that the heightened sensitivity following the experience of Mid Staffordshire would now lead to more urgent action, but, as has occurred in the past, the impact of this sort of disaster fades with time and further reorganisation.

18.212 In these circumstances, and given past experience, reliance on memoranda of understanding, with their potential for inconsistency of application and difficulties in definition and access, are not sufficient. As Dr Hughes put it:

230 EH/40 WS0000062672, para 8; GMC00000000406
231 ND/65 WS0000050311
232 ND/30 WS0000049702
233 Streets T107.70
234 Health and Social Care Act 2012, sections 288–291

... we don't need to be isolated as we were. We need to be fully integrated with the system so that we can pick up on those ... flags ... those pointers which are starting to suggest inadequate and inappropriate care so that we can actually be there at the same time.[235]

Reviews following the Healthcare Commission investigation

18.213 In June 2009, PMETB and the Deanery in their planning of future reviews chose not to arrange a visit to the Trust. In part this was because they did not consider there were continuing issues, and in part because of the existing perceived regulatory burden on the Trust following the HCC report.[236] However, since then there have been a multiplicity of reviews of training activity at the Trust:

- 4 May 2010 – to paediatrics;
- 5 May 2010 – to surgery;
- 4 June 2010 – to A&E;
- October 2010 – repeat visits to the above;
- 5 November 2010 – to the foundation programme;
- 10 November 2010 – level 1 review;
- 2012 – repeat visits.

18.214 In June 2009, the GMC produced a case study on the impact of the HCC investigation on GMC regulation.[237]

Steps taken by West Midlands Deanery since the investigation

18.215 Dr Hughes was at pains to assure the Inquiry that the Deanery has made substantial changes to its procedures since the deficiencies at the Trust were brought to light.[238] The steps taken have included:

- Training of educational leaders in how to identify patient safety issues;
- Using experience gained from the SHA "appreciative inquiry" process. According to Dr Hughes, some trusts have resisted this on the grounds that patient safety is not a responsibility of the Deanery;
- Amendment of the framework procedure to enable safety issues which are identified to be addressed;[239]
- The introduction of a common electronic induction process for trainees which includes coverage of whistleblowing, patient safety and clinical governance;

235 Hughes T114.109
236 Hughes WS0000062192, para 145
237 EH/40 WS0000062670
238 Hughes WS0000062195, paras 155–160
239 Hughes WS0000062195, para 157; EH/58 WS0000062904

- Involvement with the patient safety overview group and review of SUI reports;
- More visits on a structured basis than before;[240]
- All reports are shared with the relevant PCT cluster;
- Open access to the Dean for all trainees to raise concerns;
- Patient safety alerts provoke cross-checks against information held by the Deanery and consideration is given to whether a visit or review is required.

18.216 Dr Hughes expressed concern at what will happen following the abolition of SHAs and how the Deaneries are to remain in contact and interaction with PCTs, commissioners and others. She was concerned that much of the recent progress, as described above, might be lost in the reorganisation.[241]

18.217 Clearly the Deanery, supported by the GMC, has taken significant steps to improve the monitoring of training at provider trusts, and communication and cooperation with regulators. This process needs to continue and its benefits must not be lost in the transition to the new statutory arrangements.

The future

18.218 Deans are to be the responsible officers for trainees in training programmes under the GMC scheme for revalidation. This means that there is a stronger requirement for any concerns about trainees to be reported to them. While that should have happened in the past in any event, the Inquiry was advised that this was not invariable. The new system will have a greater degree of compulsion attached, backed up by professional sanctions. As a result Deans are likely to have a clearer picture of the concerns arising in healthcare providers.

18.219 Until now Deaneries have been part of the SHAs but these are to be abolished. While there are improvements that need to be made in the way Deaneries oversee training placements and in the approval of both Deaneries and placement programmes, local oversight is an important safeguard which should not be diluted. It is important that there is a clear structure of responsibility and accountability put in place for the functions currently performed by Deaneries.

18.220 The current proposal is that these Deanery functions will be given to Local Education and Training Boards (LETBs) under the developmental and regulatory supervision of a new special health authority, Health Education England (HEE).[242] Some LETBs may still retain a Deanery as an entity and a Dean as a separate post. HEE is to be accorded the status of a non-departmental public body (NDPB) and as such will be functionally independent of the

240 Hughes T114.105
241 Hughes T114.110–111
242 *Liberating the NHS: Developing the Healthcare Workforce* (January 2012), DH gateway ref 16977, p10, para 7, www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_132087.pdf

Department of Health (DH), its sponsor department. One of its duties will be to work with professional bodies, such as the GMC, to develop and align standards of professional training and education.[243] However, it appears that it is intended that HEE will take over the regulatory role of the GMC in respect of approving what will now be the LETBs; and it will be given powers of intervention where necessary, for example by reason of concerns for patient safety.[244]

18.221 It is important to note that HEE and the LETBs are to be responsible not just for the education and training of doctors but for all healthcare professionals, including nurses. This being the case it will be important to ensure that this structure maintains strong medical professional leadership in relation to medical training and education, as well as thorough incorporation of the patient and public interest. Without this there is a danger that matters affecting patient safety will be overlooked even more than has been the case in the past.

Conclusions

18.222 The system of regulation and oversight of medical training and education in place between 2005 and 2009 failed to detect any concerns about the Trust other than matters regarded as of no exceptional significance. There were a number of factors contributing to this:

- There was a gap in the oversight of training due to the huge changes occurring in 2005 and thereafter. This resulted in, at most, superficial oversight of the quality of training being delivered.[245]
- While patient safety was theoretically given primacy in the system, the domain to be monitored was unduly limited to the potential risk posed to patients by the trainee. It is clear that what were, in retrospect, signs of concern about safety at the Trust were given insufficient significance.
- Insufficient consideration was given to the relevance of practice to good-quality training in a setting that complied with minimum patient safety and quality standards, and to the professional obligation to protect patients from harm.
- An excessively strict exclusion of the wider ambit of patient safety from the training regulator's sphere of responsibility led to inadequate thought and action in response to concerns with implications for patient safety.
- PMETB/GMC Deanery-wide reviews focused on Deanery systems of quality management resulting in only superficial examination of the standards being observed by LEPs.
- Such reviews as took place at LEPs did not consistently consider compliance with patient safety standards.

243 *Liberating the NHS: Developing the Healthcare Workforce* (January 2012), DH gateway ref 16977, p24, para 58 www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_132087.pdf
244 *Liberating the NHS: Developing the Healthcare Workforce* (January 2012), DH gateway ref 16977, p25, para 66 www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_132087.pdf
245 Hughes T114.114–115

- When concerns were raised about inappropriate pressure or bullying by staff towards trainees these were not followed up or investigated.
- Systematic communication of indications of serious concern, such as the HCC investigation, was almost completely lacking between the regulators, and between them and the Deanery.
- A reluctance to prejudice the provision of a service or the training of trainees has resulted in the implied threat of removal of approval being largely theoretical. Patient safety must be the paramount priority in the arrangement, supervision and quality assurance of medical education and training at all levels. It is important that any suggestion of a deficiency in the training environment which may impact on patient safety is identified as such, and drawn to the attention of LEP management, education supervisors and the relevant regulators.

18.223 While requirements for remedial action must be proportionate, training should not be allowed to take place in an environment where patient safety is not being adequately protected. Perceived difficult consequences should never be permitted to hinder the steps required to protect patients, and the oversight of medical training should not condone or support unacceptable practice. As elsewhere in the system, a sense of urgency may have been lacking, even after the scale of the deficiencies at the Trust had become apparent.

18.224 The GMC appears to have become aware of the HCC's investigation through the chance of cross-membership between the HCC board and the GMC QABME team visiting Keele in May 2008.[246] The GMC was not kept informed of the progress of the investigation, or, until just before publication, of the seriousness of the findings. It should have been obvious that such an investigation could have a bearing on the adequacy of training and the safety of patients in the hands of trainees.

18.225 As Dr Hughes herself suggested to the HCC investigators, the HCC should copy the Postgraduate Dean into correspondence raising concerns, as had happened following Royal College visits in the past.[247]

18.226 Just as concerning is the failure of the HCC, the SHA and the Trust to ensure that the Deanery and/or PMETB and the GMC were aware of the letter of 23 May 2008 outlining serious concerns about A&E when it was received, as opposed to when Dr Hughes happened to contact the SHA with the concerns reported to her. That it had implications with regard to the adequacy of the department as a training environment should have been obvious.

18.227 Dr Hughes contended that "good education cannot be used as a proxy for good clinical care".[248]

246 EH/40 WS0000062672
247 EH/32 WS0000062613
248 Hughes WS0000062196, para 160

18.228 However, all doctors, whether fully qualified or in training, work in environments where they are under a duty to protect patients. Good practical training should only be given where there is good clinical care. Absence of care to that standard will mean that training is deficient. Therefore there is an inextricable link between the two that no organisation responsible for the provision, supervision or regulation of education can properly ignore. Trainees are invaluable eyes and ears in a hospital setting. They come without preconceptions, are not likely to be immediately infected by any unhealthy local culture, and are therefore perhaps more likely than established staff to perceive unacceptable practices. Concerns raised by trainees should therefore be given weight and not discounted merely because they may lack experience or qualification. Means of obtaining those concerns need to be maximised through surveys, frequent opportunities for feedback, and general support for an open and transparent culture that always puts patient welfare as the first priority.

18.229 Visits in connection with approval or accreditation of training provision and placements will inevitably always focus on the delivery of training rather than being a general inspection of service provision. Nonetheless, the experience of Stafford shows that all opportunities must be taken to exploit information from any source for the protection of patients. Training visits can and should make an important contribution in a number of ways:

- Obtaining information directly from trainees should remain a valuable source of information but it should not be the only method used.
- Visits to and observation of the actual training environment would enable visitors to detect poor practice from which both patients and trainees should be sheltered.
- The opportunity can be taken to share and disseminate good practice with trainers and management.
- Visits of this nature will encourage the transparency that is so vital to the preservation of minimum standards.

18.230 The benefits of training visits are likely to be maximised if a number of steps are taken, as set out in the recommendations below.

Summary of recommendations

Recommendation 152

Any organisation which in the course of a review, inspection or other performance of its duties, identifies concerns potentially relevant to the acceptability of training provided by a healthcare provider, must be required to inform the relevant training regulator of those concerns.

Recommendation 153

The Secretary of State should by statutory instrument specify all medical education and training regulators as relevant bodies for the purpose of their statutory duty to cooperate. Information sharing between the deanery, commissioners, the General Medical Council, the Care Quality Commission and Monitor with regard to patient safety issues must be reviewed to ensure that each organisation is made aware of matters of concern relevant to their responsibilities.

Recommendation 154

The CQC and Monitor should develop practices and procedures with training regulators and bodies responsible for the commissioning and oversight of medical training to coordinate their oversight of healthcare organisations which provide regulated training.

Recommendation 155

The General Medical Council should set out a standard requirement for routine visits to each local education provider, and programme in accordance with the following principles:

- The Postgraduate Dean should be responsible for managing the process at the level of the Local Educational Training Board, as part of overall deanery functions.
- The Royal Colleges should be enlisted to support such visits and to provide the relevant specialist expertise where required.
- There should be lay or patient representation on visits to ensure that patient interests are maintained as the priority.
- Such visits should be informed by all other sources of information and, if relevant, coordinated with the work of the Care Quality Commission and other forms of review.

The Department of Health should provide appropriate resources to ensure that an effective programme of monitoring training by visits can be carried out.

All healthcare organisations must be required to release healthcare professionals to support the visits programme. It should also be recognised that the benefits in professional development and dissemination of good practice are of significant value.

Recommendation 156

The system for approving and accrediting training placement providers and programmes should be configured to apply the principles set out above.

Recommendation 157

The General Medical Council should set out a clear statement of what matters; deaneries are required to report to the General Medical Council either routinely or as they arise. Reports should include a description of all relevant activity and findings and not be limited to exceptional matters of perceived non-compliance with standards. Without a compelling and recorded reason, no professional in a training organisation interviewed by a regulator in the course of an investigation should be bound by a requirement of confidentiality not to report the existence of an investigation, and the concerns raised by or to the investigation with his own organisation.

Recommendation 158

The General Medical Council should amend its standards for undergraduate medical education to include a requirement that providers actively seek feedback from students and tutors on compliance by placement providers with minimum standards of patient safety and quality of care, and should generally place the highest priority on the safety of patients.

Recommendation 159

Surveys of medical students and trainees should be developed to optimise them as a source of feedback of perceptions of the standards of care provided to patients. The General Medical Council should consult the Care Quality Commission in developing the survey and routinely share information obtained with healthcare regulators.

Recommendation 160

Proactive steps need to be taken to encourage openness on the part of trainees and to protect them from any adverse consequences in relation to raising concerns.

Recommendation 161

Training visits should make an important contribution to the protection of patients:

- Obtaining information directly from trainees should remain a valuable source of information – but it should not be the only method used.
- Visits to, and observation of, the actual training environment would enable visitors to detect poor practice from which both patients and trainees should be sheltered.
- The opportunity can be taken to share and disseminate good practice with trainers and management.

Visits of this nature will encourage the transparency that is so vital to the preservation of minimum standards.

Recommendation 162

The General Medical Council should in the course of its review of its standards and regulatory process ensure that the system of medical training and education maintains as its first priority the safety of patients. It should also ensure that providers of clinical placements are unable to take on students or trainees in areas which do not comply with fundamental patient safety and quality standards. Regulators and deaneries should exercise their own independent judgement as to whether such standards have been achieved and if at any stage concerns relating to patient safety are raised to the, must take appropriate action to ensure these concerns are properly addressed.

Recommendation 163

The General Medical Council's system of reviewing the acceptability of the provision of training by healthcare providers must include a review of the sufficiency of the numbers and skills of available staff for the provision of training and to ensure patient safety in the course of training.

Recommendation 164

The Department of Health and the General Medical Council should review whether the resources available for regulating Approved Practice Setting are adequate and, if not, make arrangements for the provision of the same. Consideration should be given to empowering the General Medical Council to charge organisations a fee for approval.

Recommendation 165

The General Medical Council should immediately review its approved practice settings criteria with a view to recognition of the priority to be given to protecting patients and the public.

Recommendation 166

The General Medical Council should in consultation with patient interest groups and the public immediately review its procedures for assuring compliance with its approved practice settings criteria with a view in particular to provision for active exchange of relevant information with the healthcare systems regulator, coordination of monitoring processes with others required for medical education and training, and receipt of relevant information from registered practitioners of their current experience in approved practice settings approved establishments.

Recommendation 167

The Department of Health and the General Medical Council should review the powers available to the General Medical Council in support of assessment and monitoring of approved practice settings establishments with a view to ensuring that the General Medical Council (or if considered to be more appropriate, the healthcare systems regulator) has the power to inspect establishments, either itself or by an appointed entity on its behalf, and to require the production of relevant information.

Recommendation 168

The Department of Health and the General Medical Council should consider making the necessary statutory (and regulatory changes) to incorporate the approved practice settings scheme into the regulatory framework for post graduate training.

Recommendation 169

The Department of Health, through the National Quality Board, should ensure that procedures are put in place for facilitating the identification of patient safety issues by training regulators and cooperation between them and healthcare systems regulators.

Recommendation 170

Health Education England should have a medically qualified director of medical education and a lay patient representative on its board.

Recommendation 171

All Local Education and Training Boards should have a post of medically qualified postgraduate dean responsible for all aspects of postgraduate medical education.

Recommendation 172

The Government should consider urgently the introduction of a common requirement of proficiency in communication in the English language with patients and other persons providing healthcare to the standard required for a registered medical practitioner to assume professional responsibility for medical treatment of an English-speaking patient.

Chapter 19
The Department of Health

Key themes

- The unspoken implication behind all policy changes for the NHS has been that they should be implemented safely and without exposing patients to the risk of harm or unacceptable treatment. No reform considered in this report needed to have increased any such risk if implemented in a culture which put the safety of the patient first at all times. There is no evidence that any Minister received or ignored advice that would have led to safer outcomes. No criticism of the conduct of any Minister is intended in this report's findings. In general the approach of this report is to consider the actions of the Department of Health (DH) collectively rather than on the basis of the responsibility of individual civil servants.
- Over time there has been an increasing recognition of the importance of articulating and defining the requirements of quality and safety, but the shift in culture to make aspiration a reality has yet to be completed.
- There has been recognition that there is a problem with the standard of nursing care but the problem persists in spite of various Department of Health (DH) initiatives.
- The concept of commissioning services, first introduced in the 1990s and developed in various forms, was not turned into an effective process by 2008, in part because of the limited capacity of commissioners for assessment of quality. The aspiration of World Class Commissioning to drive quality improvements as a theoretical concept was implemented before the structure and resources were in place to make it an effective reality.
- The definition of healthcare standards has evolved from combining minimum requirements and developmental standards to an attempt to identify universally required essential standards, and from process-based assessment to an attempt at assessing required outcomes. The story has been of a struggle between the rhetoric of improvement and the need for clear definition of what is acceptable.
- A clear policy that healthcare organisations should cooperate failed to ensure effective communication between Monitor and the Healthcare Commission (HCC) about the Trust. The DH had been aware of inter-organisational relationship difficulties from 2006.

- On learning of the impending HCC investigation of the Trust, apart from seeking assurance that the Primary Care Trust (PCT) was engaged in the matter, the DH approach was effectively to assume there was no cause for concern about patient safety until advised to the contrary, an approach shared throughout the system.
- The letters from the HCC to the Trust in 2008 indicating serious concerns about the Trust did not lead officials to appreciate the full gravity of the position or to procure any more urgent action to be taken. Reassurance was taken from briefings received from the HCC. As a result the Secretary of State was unaware of the serious implications of the investigation until a meeting with the HCC Chair in February 2009.
- Various initiatives have been taken to address the issue of training and support for NHS leaders, but none have flourished.
- Frequent reorganisation of the NHS structure has occurred, often taking place before the previous arrangements had been given a chance to work, and without consideration of the potential impact of the process of transition.
- Clinicians have not been at the heart of all DH decisions and activity having an impact on patient safety.
- The evidence has shown a remoteness of the DH from the reality of front-line staff and patient experience.
- While there is not a culture of bullying within the DH, an unintended consequence of its directives and policy implementation has been that on occasions they have been perceived as bullying or have been applied oppressively. Reflection is required on how to avoid such a consequence. The DH has a leadership role to play in the promotion of the required culture change.

Introduction

19.1 The Department of Health (DH) and its Ministers are responsible for the promotion of a comprehensive health service (generally free of charge at the point of delivery) and for securing the provision of hospital and other health services.[1] Behind that deceptively simple statement lies a great deal of complexity and organisational tension. The NHS is at one and the same time the largest – and it follows the most complex – healthcare system in the world, and one of the most valued assets of this country's citizens. It employs over 1.7 million people and in 2011/12 had an annual budget of around £106 billion,[2] the vast proportion of which comes from the Exchequer. Its services touch virtually every inhabitant of the country,

1 National Health Service Act 2006, section 1; now as amended by Health and Social Care Act 2012, section 1, both available at: www.legislation.gov.uk
2 Information from NHS Choices: www.nhs.uk/NHSEngland/thenhs/about/Pages/overview.aspx

with over a million people having contact with it every 36 hours.[3] Inevitably therefore, the NHS has been a major preoccupation of all Governments since its inception in 1948. In modern times the challenge has been how to reconcile the public's demand for a high-quality service, in a world of ever more sophisticated and costly methods of treatment, with increasing pressures on resources.

19.2 Professor Sir Ian Kennedy, Chair of the Public Inquiry into Children's Heart Surgery at Bristol Royal Infirmary (1998–2001) and former Chair of the Healthcare Commission (HCC), put the point in his typically pithy way:

> *... while the politicisation of the NHS is in some respects a good thing, as political commitment to the magnificent enterprise of the NHS is positive, there is an obvious tendency for the system to reflect the political ambitions of the current Government. The lack of continuity in terms of vision and the desire to tinker with the structure of the NHS may be a consequence. Whilst the NHS is separate from Government at a constitutional level, the Government of the day does not treat it as an independent entity. The distinction between the Department of State and the NHS is at best blurred.*[4]

19.3 The DH closing submissions to the Inquiry sought to draw a distinction between "accountability" to the public and "practical responsibility" for what happens locally:

> *The Secretary of State accounts to Parliament for NHS performance and its systems ... it would be neither possible nor desirable for the Secretary of State or the Department to manage the NHS operationally. The Department does not manage individual hospitals on a routine basis, and it has limited interactions with individual Trusts. NHS Foundation Trusts are not statutorily accountable to the Secretary of State. The NHS is a system run, on an operational level, by SHAs, PCTs, and provider trusts, overseen by regulators. It is ... not a single organisation. A distinction thus has to be drawn between accountability to the public, and practical responsibility for what happens at regional and local levels.*[5]

19.4 As this statement illustrates, the political direction of travel in the last 20 years has been to try to move away from central control and to devolve responsibility and accountability to local NHS organisations through various means. In particular, more recently, this has been seen through the devolution of budgets and powers to local commissioners (Primary Care Trusts (PCTs) formerly and now clinical commissioning groups (CCGs)) and through the development of the foundation trust concept. Dr William Moyes, former Executive Chairman of Monitor, told the Inquiry:

3 NHS Confederation key statistics on the NHS (updated August 2012), www.nhsconfed.org/priorities/political-engagement/Pages/NHS-statistics.aspx
4 Kennedy WS0000025840, para 17
5 CLO000000808–9, *Department of Health closing submissions,* para 19

I think that Alan Milburn would certainly have said that he found himself increasingly being called to account for operational failures in hospitals, over which in practice he had very, very little control and, therefore, what he wanted was to get to a world in which responsibility and accountability rested at the right level for the right issue.[6]

19.5 The reasoning is that healthcare can be more efficiently and effectively delivered by local organisations run by their own autonomous and accountable boards with minimal interference from Whitehall. It is considered that excessive central control stifles initiative, flexibility and improvement. At the very top, the DH has over time sought to separate itself from the NHS. This can be seen through the creation of the NHS Executive in the 1990s; the decision in 2006, following the departure of Sir Nigel Crisp, once again to split the roles of the DH Permanent Secretary and NHS Chief Executive; and, most recently, the creation of an NHS Commissioning Board under the Health and Social Care Act 2012.

19.6 The fact remains though that, through varying routes, the DH has always retained the capacity to lead the direction of the NHS. In relation to NHS trusts, the Secretary of State has always had the power of direction, and their boards have always been answerable through the hierarchy to him. In the new era of Foundation Trusts (FTs), FT boards are autonomous but nevertheless largely dependent on resources allocated to them by commissioners. Commissioners are in turn accountable to a hierarchy which itself can be directed by the Secretary of State. Therefore the means of control are undoubtedly less direct than they were, but they still exist. It is difficult to see how it could be otherwise given the significant amount of public money from the national budget that is devoted to the NHS.

19.7 If it was ever true that the clanging of a bedpan in any hospital reverberated in Whitehall, as it is said was the expectation of Aneuryn Bevan (Minister of Health at the founding of the NHS), the noise emanating from Stafford certainly did not reach the ears of the DH until it was too late to save untold suffering to large numbers of patients.

19.8 The DH has, through its senior officials, accepted before this Inquiry that the DH bears ultimate responsibility for the stewardship of the healthcare regulatory system and in that sense has to take responsibility for its failure in relation to the Trust. Sir Hugh Taylor, Permanent Secretary of the DH during much of the relevant period, said:

6 Moyes T92.97

The shocking failures of care at the trust have always seemed to me first and foremost a local failure: in leadership, governance and professionalism at the trust. But failure on the scale revealed at this Trust must also represent a failure of the regulatory and supervisory system as a whole. The DH is ultimately responsible for the stewardship of that system; and it must therefore take final responsibility for that failure. Indeed it is one we all felt deeply at the time – and continue to feel. [7]

It is clear that specific things went wrong in the regulatory and supervisory system in the case of the Trust.

- *There should have been better information sharing and closer working between the regulatory and supervisory agencies;*
- *Loss of continuity at SHA and PCT level, must have been a factor;*
- *The voices of patients and their families were missed by the regulatory and supervisory agencies as well as by the Trust;*
- *Flaws emerged in the way quality was being assessed and also in terms of the way those assessments were interpreted. More sophisticated surveillance systems are needed in terms of how trusts monitor their own governance and how this is regulated.*

The DH cannot be absolved from those failings and has to take some responsibility.[8]

19.9 It is not within the scope of this Inquiry to review everything done by the DH, but to identify the lessons to be learnt from Stafford for the future. This requires an examination of some aspects of the DH's role in the events of the last few years that set the context in which that story unfolded.

19.10 It is not necessary to examine the merits of individual policies as promoted by various Governments and Secretaries of State. That would be an arid and unproductive task. No political party and no Minister would have intentionally set policies that they knew or suspected would have allowed a disaster such as that at Stafford to have occurred. The implication lying behind any policy change would have been that it should be achieved safely and without exposing patients to the risk of harm or unacceptable treatment. There is no evidence that any Minister ignored advice that would have led to safer outcomes. This report has described numerous policy changes and directions. Even though some may have been politically controversial, there is no reason to suppose that their implementation necessarily required risks to be taken with patient safety.

19.11 Ministers are constitutionally accountable for the actions of their departments, but in practice they will not personally control much that happens in the implementation of policies. They are

7 Taylor WS0000061952–3; O'Brien T125.115–116
8 Taylor WS0000061953, paras 79–80

heavily reliant on the advice and information fed to them. Therefore, to identify accountability of the constitutional sort is likely to be unhelpful in identifying the lessons to be learnt, and it is not proposed to attempt that in this report. Accordingly, it is not intended by anything said in this chapter, or elsewhere, to be a criticism of any Minister.

19.12 Departmental civil servants only act under the authority of the Government of the day and are under a duty to deliver the Government's policy. However, just as they cannot possibly be expected to know of everything that is going on within the NHS system, they cannot be expected to report every single detail of what they do to their Ministers. They will inevitably, therefore, take some decisions and actions on the basis of their understanding of current policy. In general, it will not be any more helpful for learning lessons to single out individual civil servants for responsibility than it would be Ministers.

19.13 Therefore, the approach adopted in this report, and the report generally, is to deal with the decisions and actions of the DH corporately. However, in order for the narrative to be understood, many individuals will be identified. Some of them may wish to reflect on whether they personally could have taken different decisions or actions. However, from the perspective of learning lessons, it is sufficient generally to accept that the responsibility for the stewardship of the NHS rests with the DH collectively, but that the lessons to be learnt need to be taken on board not only by the DH collectively but also by all those who work there individually.

Departmental objectives

19.14 The DH's Annual Report 2005 set out a number of objectives for the DH. These included:

- To improve and protect the health of the population, with special attention to the needs of the poorest and those with long-term conditions;
- To enhance the quality and safety of services for patients and users, giving them faster access to services, and more choice and control;
- To deliver a better experience for patients and users;
- To improve the capacity, capability and efficiency of the health and social care systems, ensuring that system reform, service modernisation, information technology investment and new staff contracts deliver improved value for money and higher quality.

19.15 From 2008 until the general election in May 2010, the DH had three overarching objectives:

- Better health and well-being for all: helping people stay healthy and well; empowering people to live independently; and tackling health inequalities;
- Better care for all: the best possible health and social care that offers safe and effective care when, and where, people need it; and empowering people in their choices;

- Better value for all: delivering affordable, efficient and sustainable services; contributing to the wider economy and the nation.

19.16 Since the May 2010 general election, in addition the departmental objectives have been expressed as follows:

- A patient-led NHS: strengthen the patient's ability to exercise extended choice, manage their care and to have their voices heard within the NHS;
- Deliver better health outcomes: shift focus and resources towards better health outcomes including national health outcome measures, patient reported outcomes and patient experience measures;
- More autonomy and accountability: create a long-term sustainable framework of institutions with greater autonomy from political interference and greater accountability to patients and the public, focused on outcomes;
- Improve public health: promote better public health for the nation by centring the Department's focus on public health, developing a clear strategy and partnering with businesses;
- Reform long-term care: improve accessibility and options for long-term home and domiciliary care by focusing on prevention rather than costly care, personalisation and partnerships for delivery.

19.17 There is clearly a common theme across all the DH's objectives in these years of improvement. Whilst there is nothing irregular in having such objectives, and many would think them essential to set direction and establish priorities in such a large organisation, it is important not to lose sight of what must underpin such aspirations, namely to maintain fundamental standards of safety and quality.

Development of quality and safety policy

19.18 Throughout the 1980s and 1990s, quality and safety were considered to be a matter of individual professional obligation and judgement, rather than a matter for policy. Professor Sir Liam Donaldson, Chief Medical Officer (CMO) from 1998 to 2010, described to the Inquiry how quality policy had initially been the domain only of experts and enthusiasts:

> *At that time* [the 1980s – early 1990s] *the mainstream of health professionals, health care managers, policy-makers and politicians took no sustained interest in developing policies and ideas that would transform the quality of care being provided to patients. The safety of care was not a recognised concept beyond statutory requirements covering areas such as: fire hazards, environmental and building standards and quality assurance of medicines and devices.*[9]

9 Donaldson WS0000070106, para 13

19.19 By 1998, when Sir Liam took up post as CMO, the concepts of quality and safety had developed further. A number of factors had combined to focus attention increasingly on the need for the health service to improve safety and prevent harm. These included healthcare scandals in this country and elsewhere in the late 1980s and early 1990s (usually involving single practitioners), experience over a number of years of whole-system failures (the most recent of which had occurred in children's heart surgery at Bristol Royal Infirmary[10]), and persistent incidents of medical error.[11]

19.20 Sir Liam devised and championed the concept of clinical governance, which was formally set out in the DH document *A First Class Service*, published in July 1998. The document set out a three-part strategy for quality improvement. This consisted of national standards (in which the National Service Frameworks for major conditions such as cancer, coronary heart disease and older people, and the role of the National Institute for Health and Clinical Excellence (NICE) were important elements); local delivery through clinical governance; and inspection through the Commission for Health Improvement (CHI).[12] The document also set out a number of key components of clinical governance. These included the following, which Sir Liam described as "revolutionary" at the time:[13]

- Clear lines of responsibility and accountability for the overall quality of clinical care;
- A comprehensive programme of quality improvement activities, for example full participation by hospital doctors in clinical audit;
- Clear policies aimed at managing risks;
- Procedures for all professional groups to identify and remedy poor performance, for example through critical incident reporting and learning from complaints.[14]

19.21 In his evidence, Sir Liam gave two key purposes of clinical governance. The first was to establish a duty beyond the care of individual patients to ensure that action, and opportunities, were taken to improve the quality of service. The second was to establish the principle that the patient's interests were paramount and that it was not acceptable to turn a 'blind eye' to the bad practice of a colleague.[15]

19.22 The report *An Organisation with a Memory*, published in 2000, made clear the scale of harm caused to NHS patients and the problems of failure to learn from mistakes. It highlighted the challenge of a "culture of blame" which led to defensiveness and a reluctance to adopt systems that would expose and punish individual failings. Instead, it proposed to move away

10 The Bristol Royal Infirmary Inquiry Learning from Bristol: The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984–1995 (July 2001)
11 Donaldson T122.5–6
12 Donaldson WS0000070113, para 30
13 Donaldson T122.18
14 LD/3 WS0000070255–6
15 Donaldson WS0000070112, para 25

from individual blame to a recognition that systems played their part. As the executive summary to the report put it:

> *When things go wrong, whether in health care or in another environment, the response has often been an attempt to identify the individual or individuals who must carry the blame ...*
>
> *It is of course right, in health care as in any other field, that individuals must sometimes be held to account for their actions – in particular if there is evidence of gross negligence or recklessness, or of criminal behaviour. Yet in the great majority of cases, the causes of serious failures stretch far beyond the actions of the individuals immediately involved ...*
>
> *Human error may sometimes be the factor that immediately precipitates a serious failure, but there are usually deeper systemic factors at work which if addressed would have prevented the error or acted as a safety net to mitigate its consequences.*[16]

19.23 In his evidence to the Inquiry, Sir Liam highlighted the concept of "honest failure" or, in other words, a culture in which a person who has made an error can hold up their hands to failings and openly seek to put them right:

> *Honest failure is something that needs to be protected otherwise people will continue to live in fear, will not admit their mistakes and the knowledge to prevent serious harm will be buried with the patient.*[17]

19.24 The challenge has been not with the correctness of these principles but with ensuring their acceptance, adoption and implementation by front-line professionals. Nowhere was this illustrated more powerfully than in the report of the public inquiry into children's heart surgery at Bristol Royal Infirmary, which was published in July 2001.[18] The Bristol Inquiry identified a professional club culture that had contributed to poor care, and drew attention to the importance of clinical audit and governance. In his evidence, Sir Ian Kennedy, who chaired that Inquiry, highlighted a number of principles that had been set out in his Inquiry report and which he felt were of particular note in the context of the later events at Mid Staffordshire:

- Consistency of direction;
- The legitimate needs of patients must be at the centre of the NHS;
- A first condition for achieving quality in healthcare is that the service is safe; once safety, as a fundamental prerequisite, has been addressed, attention must turn to the pursuit of quality;

16 LD/5 WS0000070414–5
17 Donaldson WS0000070116, para 39
18 The Bristol Royal Infirmary Inquiry Learning from Bristol: The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984–1995 (July 2001)

- To secure care of high quality across the NHS, those elements of the service that go beyond technical skills and competence and beyond the systems in which they are practised must not be overlooked; it was important to care about attitudes.[19]

19.25 A further development occurred with the establishment of the National Patient Safety Agency (NPSA) in 2001, following a recommendation set out in *Building a Safer NHS for Patients: Implementing an Organisation with a Memory* (published in April 2001).[20] In 2003, the NPSA launched the National Reporting and Learning Service (NRLS), which provided a mechanism for the confidential reporting of patient safety incidents. The system was similar to that adopted by the aviation industry and by the end of 2005 had been rolled out to the NHS.[21]

19.26 Contrary to the recommendation in *An Organisation with a Memory*, the NRLS was set up as a voluntary rather than mandatory reporting system, because of a perceived need to build professional confidence in the system. As Dr Suzette Woodward explained in her evidence to the Inquiry:

> *A voluntary system relies on people wanting to report patient safety incidents. I suspect that those introducing NRLS at the time felt that if it was a mandatory system, organisations would think of the NPSA as an NHS performance manager, rather than what it was, a learning based organisation ... Self-reporting of incidents is not designed to detect failure or problem trusts; it was designed to facilitate learning from such incidents.*[22]

19.27 This position changed from April 2010, when the registration requirements of the Care Quality Commission (CQC) made the reporting of severe harm and death incidents compulsory.

19.28 In July 2004, the DH published *Standards for Better Health*, a set of national standards by which the HCC would rate NHS trusts from April 2005 onwards. The standards were divided into "core standards" (which all organisations should achieve as a minimum) and "developmental standards" (to which organisations should aspire). There was significant debate at the time about the extent to which the standards should focus on outcomes (as favoured by Sir Ian Kennedy, then Chair of the HCC), as opposed to systems or processes (as favoured by Ministers). This perhaps reflected the difficulty of ensuring the standards captured that which could be measured – the difficulty of measuring quality at this time was a point raised by Professor Sir Bruce Keogh, NHS Medical Director, in his evidence.[23] The evidence on this point is considered in *Chapter 9: Regulation: the Healthcare Commission*. The debate showed the difficulties of getting the balance right between what professionals thought was

19 Kennedy WS0000025837, para 7
20 Donaldson WS0000070151, para 143
21 NPSA WS (Provisional) NPSA00000000012–13, para 3.5
22 Woodward WS0000044970, para 17
23 Keogh T123.26

possible, or would be workable, and a political imperative that standards reflect what was seen as the important factors driving public concern.

19.29 Una O'Brien, Permanent Secretary of the DH, acknowledged that the regulation of quality was a new concept and reflected that:

> *... to a degree, the regulatory model was always going to be developmental. It needs to be recognised that this was a new approach, developed alongside the management of organisations, and it was a process of learning, adapting, and improving.*[24]

19.30 The points made by the Rt Hon Andy Burnham MP (a former Secretary of State for Health)[25] and Sir Liam[26] indicate that the focusing of the assessment of compliance on self-declarations with an all-embracing requirement told one little of the real state of affairs. It may be thought that one reason for this was combining in a standard concepts of minimum quality with aspirational requirements and an emphasis on improvement, rather than identification of a baseline and movement from that.

19.31 A standard is something that should be applicable to the care given to every patient individually. Then it can be as detailed as anyone could wish: it is not about requiring a dramatic increase in resources but an evidence-based assessment of what is the minimum that can be achieved with available resources.

19.32 From 2005, the financial context in which the NHS operated changed significantly. Richard Douglas, the DH's Director General of Finance and Investment at the time, described this for the Inquiry in his provisional statement. The period from 2001/02 to 2006/07 was one of unprecedented growth, with total revenue funding increasing by an average of 8.7% per annum (with PCT revenue allocations increasing by an average of 9.4% per annum).[27] In the first two years of this period the NHS as a whole delivered a small revenue surplus, but in 2004/05 and 2005/06, the NHS moved into deficit, before recovering the following year:

> *Historically, the NHS had operated at the margins, with annual spending matching or slightly exceeding budget. However, it was clear in 2005–06 that action needed to be taken to put the NHS on a more sustainable financial footing and to turn round the deficit.*[28]

24 O'Brien WS0000059314, para 27
25 Burnham T115.12–3
26 Donaldson T122.90
27 Douglas WS (Provisional) DH00000002660, para 7
28 Douglas WS (Provisional) DH0000002661, paras 11–12

19.33 On 28 June 2005, the Rt Hon Patricia Hewitt MP, then Secretary of State for Health, wrote to the chairs of all NHS trusts and PCTs that had reported significant deficits (over 1%) in their 2004/05 draft accounts (around 99 organisations):

> *The Government had made, and is continuing to make, unprecedented investment in the NHS. With this investment comes a responsibility to deliver not only improved services but also the best possible value for money.*
>
> *... I am concerned that organisations like yours now face more serious financial challenges. These are not going to be resolved by additional income but by better management of costs. I am sure you will agree that this is a major responsibility for you and your fellow non-executives.*[29]

19.34 On the same day, Sir Nigel Crisp (then DH Permanent Secretary and Chief Executive of the NHS), wrote to the chief executives of all NHS organisations with a deficit in their draft 2004/05 accounts (around 130 organisations). His letter saw poor financial management as putting at risk improvements in performance:

> *I was disappointed to note that your organisation will report a deficit for the financial year 2004/05 in your annual accounts ... This is an unsatisfactory situation.*
>
> *I recognise that we face a challenging agenda, and that staff at all levels of the service have worked extremely hard over the last year. It is due to these efforts that we have seen impressive improvements in performance across the NHS in a range of areas. This has helped to maintain and even enhance the reputation of the NHS as a highly valued public service. We cannot allow poor financial management to put this at risk.*
>
> *Poor financial management in a few organisations can erode public confidence in the management of the NHS as a whole. For the NHS to protect its growing reputation as an effective public service, all organisations must pursue their financial duties with as much vigour and determination as they do other key priorities.*[30]

19.35 The letter gave a strong message that additional financial support would be limited and that local delivery plans forecasting a deficit or based on unrealistic assumptions would not be accepted. It also attached, as an annex, a document called *Ten High Impact Changes*, which had been developed and published by the Modernisation Agency in September 2004 and set out the areas these organisations should address, requiring better care while reducing costs.

29 Douglas WS (Provisional) DH0000002669, first exhibit
30 DN/12 WS0000068078

It stated that this provided "a well-evidence based approach to delivering better care for patients, while reducing costs".[31,32]

19.36 Whilst this language emphasised that good financial management underpinned good care, it is worth asking whether the DH was demanding the impossible by suggesting such cuts could be made without impacting on services. In practice, there is little evidence to suggest the DH had any means of knowing whether or not this was the case. Sir David Nicholson, NHS Chief Executive, was asked about this by the Public Accounts Committee in October 2006 when he made it clear that the DH was reliant on local bodies to assess these matters:

> *Chairman: we have read a lot recently about the deficits causing redundancies and ward closures throughout the country. How will you ensure that essential services in "NHS are maintained, if not improved?"*
>
> *A ... That essentially is a local matter. All those issues play slightly differently in each local circumstance. We are dependent on local PCTs and NHS trusts reaching arrangements that suit them overall. Obviously each organisation has put its plans to the* [SHA]*, and we have looked at them overall. We are satisfied that the development in health services in the NHS over the next 12 months will deliver the things that we want to deliver in respect of the six priorities identified by the Department. Each organisation goes through its planning process. They have to identify that they must deliver their waiting times and so on, and we are satisfied that that is what they are currently doing.*[33]

19.37 The Public Accounts Committee's report, published in February 2007, found that:

> *The Department does not have an overall picture of the impact of deficits on the NHS's capacity to deliver services, and was only able to provide us with information about the number of redundancies, closures and abandoned capital programmes after our hearing. Decisions on structuring and staffing in individual organisations are taken at a local level, but the Department should collect this information as part of its wider performance management arrangements so that decisions affecting the capacity of the NHS to deliver its objectives are properly informed.*[34]

19.38 Sir David accepted in his evidence to the Inquiry that this was the position. He pointed out that the position was different today, in particular because of the development of an electronic staff record.[35]

31 DN/13 WS0000068083
32 DN/13 WS0000068083
33 Nicholson T127.73
34 Nicholson T127.72; DN/15 WS0000068099
35 Nicholson T127.75–76

19.39 At the time, the DH delegated the oversight of financial and performance management to PCTs via the lever of commissioning and to SHAs as performance managers. This approach was described by Alan Hall, Director of Performance at the DH:

> *Our approach to performance management has been that priorities need to be clearly articulated at national level, with delivery plans owned and achieved locally. The prime responsibility for service delivery is that of the Board of the local NHS provider. When performance does not meet the required standards, it is then a matter for the local PCTs as the commissioner of services, to hold the provider organisation to account … In the case of a significant failure to deliver or continued underperformance at local level, I work closely with the SHA to escalate the issue with the PCT.*[36]

19.40 The DH continued to monitor trust-level performance indicators, but none of the indicators spotted a problem at the Trust.[37] The DH did not use the staff survey or patient survey to check on individual trusts' performance and expected local organisations to deal with local problems, assuming they would do so.[38]

19.41 The truth is that the DH was focused on financial performance and assumed that providers would maintain standards whilst reducing costs. Part of the rationale was that good financial management brought good clinical performance with it.[39] This was explained by Sir David:

> *This was not about trading off quality of care with financial control. The two can and should go hand in hand. For example, a typical case of MRSA costs the health service £7,000 and for C. difficile the figure is £10,000. Reducing incidences of HCAIs* [healthcare associated infections] *therefore saves money and improves quality.*[40]

19.42 Sir Liam recognised that safety, despite being a declared priority within the DH since the publication of *An Organisation with a Memory*, had not been given the same priority as financial and access targets within the NHS. He agreed that this was in part due to the greater difficulty in measuring safety as opposed to financial performance.[41] This concern to promote patient safety led Sir Liam to commission the DH document *Safety First*, which was published in 2006. In his preface, Sir Liam stated that:

> *An overriding message of this report is to restate the importance of strong leadership within NHS organisations. Safety does not have the priority it needs at the top of all our healthcare organisations. This must change if we are really going to put 'safety first'.*[42]

36 Hall WS0000064385–6, paras 17–18
37 Hall WS0000064397, para 60
38 Hall WS0000064389–90, para 29
39 Nicholson WS0000067639, para 36
40 Nicholson WS0000067639, para 36
41 Donaldson T122.101
42 LD/25 WS0000070821

19.43 Elsewhere, the document was frank about the challenge:

> *Championing at a national level has raised the profile of patient safety. However, patient safety is too often seen by NHS Boards and managers as not having the same priority as achieving financial and access targets.*
>
> *... there is a perception that the NHS has not yet fully embraced patient safety as a key organisational priority. This has been compounded at times by inconsistent messages about priorities being given by the Department of Health.*[43]

19.44 An insight into the DH's approach to policy and delivery at the time is provided by the capability review of the DH, which was carried out by the Cabinet Office in June 2007. The Department was criticised for lack of leadership, in not yet setting out a clearly articulated vision for the future of health and social care, and instead operating often as a collection of silos, where corporate governance structures were not as effective as they needed to be.[44] At the same time, the DH was praised for securing some significant delivery achievements:

> *The Department's capability to manage and track performance across the NHS system is impressive and central to the successful delivery of targets. It has found ways to collect and analyse real-time date from the NHS.*
>
> *This has allowed it to grasp performance issues firmly and respond swiftly, where necessary. There have been notable successes in identifying and deploying appropriate interventions at a local level, such as in the use of turnaround teams in underperforming accident and emergency departments.*[45]

19.45 Successful delivery, from the perspective of the Cabinet Office, was identified closely with delivery of the key Government targets (particularly the Public Service Agreements, or PSAs, agreed with the Treasury and Number 10) and financial balance. A particular achievement was the DH's strengthening of its planning and resource management capabilities, making significant progress in tackling NHS deficits.[46] However, it was also found that:

> *Management of risk across the delivery chain is weak. There is no formal linkage between risk registers and mitigation strategies held by the Department and those in the delivery chain.*[47]

43 LD/25 WS0000070835–6, pages 19–20
44 DN/61 WS0000068760
45 DN/61 WS0000069765–6
46 DN/61 WS0000069766
47 DN/61 WS0000069767

19.46 One identified area for action was for the DH to improve its capability for planning the implementation of policy:

> *The Department needs to develop processes for ensuring the robustness and consistency of the Department's policy implementation planning.*
>
> *It should ensure delivery partners and stakeholders are consistently engaged earlier in the development of policy implementation plans.*
>
> *It should ensure that risks are identified, owned and managed to minimise the likelihood and impact of problems in delivery. This risk analysis should encompass the impact on other DH policies and on the interests and behaviours of internal and external stakeholders.*[48]

19.47 When the Cabinet Office returned in July 2009 to assess the DH's progress and next steps, it identified significant improvements in leadership and in strategic and analytical capabilities. It pointed to the DH's strong delivery culture and successful overall delivery performance of its PSAs, but highlighted the fact that:

> *The increasingly devolved delivery system is complex, with the roles and responsibilities within it not always understood.*
>
> *... Despite improvements, many stakeholders and other Government departments still find the department complex to understand and difficult to navigate.*
>
> *... Roles and responsibilities of the different bodies within the health delivery system are not always clear and understood by stakeholders and delivery partners. In some cases this has led to inefficiencies and tensions.*[49]

19.48 The importance of quality was recognised explicitly by the Government in 2007/08 with the establishment of Lord Darzi's Next Stage Review (NSR). As part of the work underpinning the NSR, which included widespread visits and consultations with interested parties, Sir Liam chaired a quality improvement working group. Lord Darzi, like Sir Liam himself, felt that quality had previously been afforded less prominence than the achievement of targets and financial balance. At the first meeting of the working group in November 2007, the minutes record Lord Darzi making the following observation:

> *The 2000 review was all about systems reform: how do you reform the NHS, make it more transparent and what are the business lessons. Yet we missed the key thing: quality of care.*

48 DN/61 WS0000068770
49 DN/62 WS0000068787–8

The CMO has been banging on about quality and safety but staff on the shop floor have to think about payment by results and private finance initiatives not quality.[50]

19.49 As part of his work leading the working group, Sir Liam commissioned reports from three highly respected US-based organisations: the Joint Commission International (JCI), the Institute for Healthcare Improvement (IHI) and Rand Health.

19.50 The Rand report focused on the development, dissemination and assessment of standards, highlighting the need for a coherent vision of the role of standards and systematic approaches to integrating clinical guidelines with quality measures development. It emphasised the importance of information and data, and advised a focus on improving the functioning of existing organisations before entertaining the development of new organisations.[51]

19.51 The JCI report looked at quality oversight in England. It highlighted the following key themes:

- A "shame and blame" culture of fear appearing to pervade the NHS and certain elements of the DH;
- Some significant flaws in the DH's then current quality oversight mechanisms – these included a 'top-down' approach to the development of standards, lack of co-ordination with the DH in the development of standards, and an assessment process based on self-assessment and light-touch regulation;
- A philosophy of gathering large amounts of quality and safety related data before deciding the specific purposes for which it will be used;
- Performance improvement driven by targets;
- A strong emphasis on decentralisation, but accompanied by lack of standardisation in the performance measures applied and the data gathered;
- Quality not driving or even influencing commissioning decisions, which lacked standardisation;
- Multiple entities with oversight of trusts and PCTs, with overlapping standards and/or responsibilities;
- Lack of oversight of physician performance and of physician engagement in the development of important quality oversight and improvement resources, with the exception of NICE guidelines;
- Constant churn and lack of training for chief executives, and lack of engagement of these with clinicians;
- Manpower issues, with an excess of physicians in relation to training posts, but lack of funding for nurse education and posts;
- Scepticism about the legislation to introduce the Care Quality Commission (CQC).[52]

50 LD/27 WS0000070880
51 KM/12 PA0002000004–5
52 KM/12 PA0002000057–62

19.52 Importantly, the report observed that there was no systematic effort to derive relevant clinical performance measures from NICE and no standard measure of patient experience. It commented on the potential for "gaming" in relation to targets.

19.53 The IHI report looked at achieving the vision of excellence in quality, and made the following eight recommendations:

- Develop a widely shared view of the overall system for improvement in the NHS – at present it was felt the efforts and messages of the different stakeholders and bodies could sometimes clash or interfere with each other;
- Establish and persist in the expectation that patients and families will be actively involved in design and improvement at national, local and microsystem levels – the report highlighted the virtual absence of mention of patient and families in the overwhelming majority of conversations;
- Develop a comprehensive, balanced set of system-level measurements for learning, benchmarking and public transparency – the report was critical of the numerous, disaggregated targets;
- Heal and rebuild relationships between clinicians and managers at all levels, from national to health economies;
- Foster stability of relationships and leadership; use the structures already in place – the report strongly counselled against additional restructuring of NHS agencies, regulators or care-system components;
- Foster a culture of learning and innovation, balanced with accountability – the report suggested that whilst some top-down mandates and aims are likely to be necessary and appropriate, NHS leaders should foster more confidence, risk-taking, learning and cooperation among system elements and roles;
- Build capability for improvement, especially in local care systems;
- Develop an understanding of the production of health and healthcare as a system in the NHS.[53]

19.54 The reports are revealing in their insight into the DH's approach to quality and safety matters at the time. Whilst they varied in tone, each highlighted significant issues, focusing on the culture set by the DH, the lack of a coherent strategy and approach in relation to quality, and tensions in the relationships throughout the system between organisations, managers, clinicians and the DH.

19.55 Senior witnesses from the DH, including Sir Liam, Sir David, and David Flory (Director General of Finance, Performance and Operations and Deputy NHS Chief Executive at the DH), were highly critical of aspects of these reports in their evidence to the Inquiry, particularly that produced by JCI with its accusation of a 'bullying culture' at the DH. Sir Liam accepted the

53 KM/12 PA000200081–82

reports showed the culture of the NHS was not far enough along the quality journey, but also emphasised IHI's conclusion that the NHS had the potential to become a system that leads the world in terms of equity and quality.[54] Sir David accepted some of the criticisms made by JCI, although he disagreed with its overall analysis of the English healthcare system. He pointed out that these reports had been commissioned in order to gather a range of answers, and parts of the reports were very influential in the way the NSR was taken forward.[55] Indeed it is clear that the NSR, considered below, sought to address many of the concerns raised in these reports.

19.56 In June 2008, *High Quality Care for All – NHS Next Stage Review final report* was published. The report set out three distinct dimensions to "quality":

- *Patient safety – the first dimension of quality must be that we do no harm to patients. This means ensuring the environment is safe and clean, reducing avoidable harm such as excessive drug errors or rates of healthcare associated infections.*
- *Patient experience – quality of care includes quality of caring. This means how personal care is – the compassion, dignity and respect with which patients are treated. It can only be improved by analysing and understanding patient satisfaction with their own experiences.*
- *Effectiveness of care – this means understanding success rates from different treatments for different conditions. Assessing this will include clinical measures such as mortality or survival rates, complication rates and measures of clinical improvement. Just as important is the effectiveness of care from the patient's own perspective which will be measured through patient-reported outcomes measures. Examples include improvement in pain-free movement after a joint replacement, or returning to work after treatment for depression. Clinical effectiveness may also extend to people's well-being and ability to live independent lives.*[56]

19.57 The report then sets out a seven-part framework for achieving these goals:

- To be clear what high-quality care looks like in all specialities and reflecting this in a coherent approach to the setting of standards;
 - This would mean developing the role of NICE in expanding the number and reach of national quality standards.
- Measurement of quality;
 - This would mean the development of a national quality framework and metrics, and of clinical dashboards.
- Publishing quality performance;

54 Donaldson T122.112–113
55 Nicholson T127.86; Nicholson WS0000067723, para 299
56 LD/30 WS0000071051

 - Healthcare providers working for or on behalf of the NHS would be required in legislation to publish quality accounts.
- Recognising and rewarding quality improvement;
 - The payment system for providers would be improved and local improvement would be supported by the Commissioning for Quality and Innovation (CQUIN) scheme.
- Raising standards;
 - Improving standards by stronger clinical leadership, particularly at SHA level, with each SHA asked to establish a Quality Observatory, and at national level through creation of a National Quality Board.
- Safeguarding quality: the role of intelligent regulation;
 - The role of the new Care Quality Commission.
- Staying ahead: a pioneering NHS;
 - Promotion of innovation and research.[57]

19.58 Sir Liam Donaldson characterised this review as the culmination of a decade of working towards putting quality at the centre of the NHS agenda.[58]

19.59 This report was undoubtedly a seminal moment in the recognition of the importance of redefining quality and finding ways of measuring it in a much more sophisticated fashion than had previously been the case. It sought laudably to set out a definition, and propose measurement methods and incentivisation. What now needs review is whether safety and certain other fundamental standards ought to be redefined as a pre-condition to the provision of a quality service rather than be part of the definition of quality itself. Safety and fundamental standards need to be focused on as the priority and not be capable of being lost in claims for "improvement".

19.60 To date *High Quality Care for All* has not produced the success that might have been hoped. This was evidenced by the HCC's valedictory report published in March 2009, which stated that:

> *In the NHS, while overall performance in meeting core standards has improved, the attention given by the system to getting core standards in place, and then, since they are core standards, moving performance along a trajectory of improvement, has not been adequate ... this inadequate level of performance does not even get a mention in the Operating Framework for the NHS for 2009/10. It may be that the political pressures in the system are more concerned with certain specific targets which are readily measured than with the less easy to document, but fundamentally more important, general achievement of a set of standards for everyone.*[59]

57 LD/30 WS0000071052–61
58 Donaldson WS0000070142, para 115
59 UOB/16 WS0000059716–7

19.61 The House of Commons Health Select Committee's report on patient safety, published in June 2009, similarly stated that:

> *The Government is to be praised for being the first in the world to adopt a policy which makes patient safety a priority. However, Government policy has too often given the impression that there are priorities, notably hitting targets (particularly for waiting lists, and Accident and Emergency waiting), achieving financial balance and achieving Foundation Trust status, which are more important than patient safety. This has undoubtedly, in a number of well documented cases, been a contributory factor in making services unsafe.*[60]

19.62 This suggests that quality still has not been given a sufficient priority. Sir Liam's explanation was that there was a need for a cultural shift in attitudes through the system, and he was positive about the capacity for change to be brought about "top down", by people at the top of the system:

> *... there's a lot of debate always about top-down and bottom-up, but there is no question in my mind that given the service is as it is and has been quite hierarchical ... if the people at the top are speaking about a subject or a theme regularly, then ultimately those delivering the service at operational level will do.*[61]
>
> *I gave a huge number of conference speeches and was always talking about quality, but not everybody was, and that's not a criticism, it's just that I'm not sure that in their heart of hearts everybody was convinced that you could run a service which met the financial and productivity targets but also delivered quality ...*
>
> *... it was – advocacy – constant advocacy and persuasion, until eventually, around the time of Lord Darzi's report and subsequently, the top people are now saying quality, quality, safety, safety, and then the NHS listens.*[62]

19.63 The importance of culture was also set out in the evidence of Una O'Brien, the DH Permanent Secretary, but with a different emphasis on the limitations of what could be achieved "top down" as opposed to "bottom up":

60 KM/13 PA0002000172
61 Donaldson T122.20
62 Donaldson T22.21–22

I do think that the drivers of culture in the NHS are many and complex and, indeed, you know, I know looking at it from the perspective of the clinical front line, the Department of Health is not the first place that people want to or indeed ought to be listening to when it comes to the way in which they do their jobs. What they need to be doing is listening to and engaging with patients, and not with something that's coming out of a Government department.

So I'm reticent to overclaim for anything the Department as an organisation can or should do, other than in a sense respond to, if you like, the priorities set by the Government of the day and their response to the electorate for change, or things that are coming up from the front line that actually say we need a stronger framework as such.[63]

19.64 The National Quality Board's (NQB's) report *Review of Early Warning Systems in the NHS*, published in February 2010, indicated that the necessary "cultural shift" had not yet occurred. Chapter 2 of the report looked at what it meant to put patients first and the culture that was needed across the NHS system to make this a reality:

The NHS is a complex system, not a single organisation; therefore, this culture needs to reach beyond organisational boundaries. The whole system, from individual clinicians to politicians in Government, has a part to play in fostering a culture of openness, transparency and cooperation. We need to shift the culture of the system from one of reluctance and blame, where failings automatically result in a race to point the finger, to one of openness, learning and continuous improvement.[64]

19.65 Whilst matters of patient safety and quality have clearly moved up the DH's agenda therefore over the past 10–15 years, it is clear there is still some way to go before quality, and the open culture on which it is contingent, genuinely and effectively become the organising principles of the NHS envisaged in Lord Darzi's review. To that extent, the "paradigm shift" described by Una O'Brien from 2006 is not yet complete.[65]

Nursing issues

19.66 As set out in *Chapter 23: Nursing*, the first inquiry report contained many examples of totally unacceptable nursing care, behaviour and attitude.

19.67 It has been apparent for some time that there have been problems with the standards of nursing. In her evidence to the Inquiry, Dame Christine Beasley, then Chief Nursing Officer for England (CNO) at the DH, reflected on the development of the nursing profession in recent years. She emphasised that a stronger focus on education for nurses complemented, rather

63 O'Brien T125.145
64 UOB/28 WS0000059983
65 O'Brien T125.133

than undermined, their ability to care compassionately and to carry out basic nursing tasks. However, she also felt the rapid expansion of the nursing workforce in the 1990s was conducted, in her view, without enough attention to "values and behaviours":

> *I think nursing did lose its way. I think in the times when we were growing the nursing workforce rapidly ... I think in doing that, not enough attention was paid to values and behaviours, and in some cases also to academic achievement.*[66]

19.68 By 2007, she said, various incidents and reports (such as the HCC's report on nutrition, and its report on healthcare infections at Maidstone and Tunbridge Wells) highlighted variations in nursing quality. Dame Christine accepted that this suggested a national phenomenon and was not just a matter of one or two rogue organisations.[67]

19.69 Various reports throughout 2010 and 2011 suggested matters had not greatly improved since. Age UK's report of August 2010, *Still Hungry to be Heard,*[68] the Parliamentary and Health Service Ombudsman's (PHSO's) report *Care and Compassion? Report of the Health Service Ombudsman on ten investigations into NHS care of older people*, published on 14 February 2011,[69] and the CQC's dignity and nutrition inspection programme national overview, published in October 2011,[70] all pointed to problems with the provision of basic and compassionate nursing care. Commenting on these, Dame Christine said:

> *I think* [the problems highlighted in 2007] *have improved, but you're absolutely right, they've not been eradicated. I think we still have a real challenge in hospital care around the complex needs of our most vulnerable patients, which tend to be older people with a lot of complex conditions and who are normally, not exclusively, but who are normally in medical wards ... that area ... is still very challenging for us all, and I don't think we've got it right.*[71]

19.70 A national benchmarking system for standards of nursing care, *Essence of Care* (EoC), had been launched in 2001, setting out 12 benchmarks along with tools for achieving them. Dame Christine described the system in some detail in her statement to the Inquiry, summarising it in the following terms:

66 Beasley T117.14
67 Beasley T117.20
68 *Still Hungry to Be Heard: The scandal of people in later life becoming malnourished in hospital* (Aug 2010) Age UK: www.ageuk.org.uk/get-involved/campaign/hungry-to-be-heard
69 AA/16 WS0000053979; also available at: www.ombudsman.org.uk/care-and-compassion/home
70 CQC00000000394 Care Quality Commission (Oct 2011) *Dignity and Nutrition Inspection Programme: National overview* www.cqc.org.uk/public/reports-surveys-and-reviews/themes-inspections/dignity-and-nutrition-older-people
71 Beasley T117.31–32

EoC is ultimately a self-improvement mechanism for teams to ensure they reach the standards required. It has been developed to help create a local culture of improvement and there are no national sanctions associated with it. Although no national evaluation of the programme has been undertaken, the anecdotal evidence provided locally is both positive and plentiful.[72]

19.71 She accepted that there had been no national evaluation of these benchmarks, to the extent that the DH did not know what the take-up of them was, but explained that it was difficult to achieve an evaluation that was cost effective.[73] As such, this is a potentially good idea floated by the DH but not followed through.

19.72 Dame Christine also recognised that nurse staffing levels were crucial to maintaining good outcomes for patients.[74] However, she had never issued guidance, because she considered there was a danger of over-simplification and of such guidance being treated as setting a maximum rather than a minimum level of staffing.[75] She generally agreed with the approach in the Royal College of Nursing's (RCN's) policy paper, *RCN Policy Position: Evidence-based nurse staffing levels*, which included a list of key indicators on staffing that should be routinely monitored by providers, commissioners and regulators, and gave a benchmark average of 65% registered nurses on general hospital wards.[76] However, the DH had not published any support for it.[77]

19.73 Dame Christine also highlighted the Safer Nursing Care Tool as one tool that would have been available to the Trust to help it determine an appropriate registered to unregistered nursing staff level. Dame Christine had taken part in the development of the Safer Nursing Care Tool, but emphasised that its use was not nationally mandated. Instead, it was one of the most recent of a number of tools available to senior nurses. No attempt had been made by the DH to require its use as it might not be appropriate in every setting.[78]

19.74 Successive Governments have opposed the introduction of regulation for healthcare support workers, on the grounds that it would not be proportionate. This was the case although the CNO had participated in the Prime Minister's Commission on the Future of Nursing, which had recommended some form of regulation for this group.[79] This issue is discussed in *Chapter 23: Nursing*.

72 Beasley WS0000051816
73 Beasley T117.38–41; WS0000051816, paras 69–71
74 Beasley T117.52–53
75 Beasley WS0000051810, para 50
76 RCN0001000013 *RCN Policy Position: evidence-based nurse staffing levels* (Dec 2010) Royal College of Nursing
77 Beasley T117.57–58
78 Beasley WS0000051812, para 56; Beasley T117.72–74
79 Beasley T117.121–124

19.75 There has been a Governmental and a departmental recognition that there is a problem with the standard of nursing care, which impacts directly on the experience of patients; the Government and the DH have responded with tools and reviews without producing any concrete policy to bring about change. Sir David Nicholson suggested that it would be better to focus resources on training and education[80] rather than regulation, but it is not clear this has been done. In the meantime, it is clear that the problem has persisted.

19.76 The DH is, as it accepts, ultimately responsible for the stewardship of the system, but it does not directly manage the nursing workforce, control the standard setting, education or training which are within the domain of the Nursing and Midwifery Council (NMC). Therefore, the DH is best able to contribute to the solution of the problems in nursing by offering support, appropriate resources and monitoring of their effectiveness. This could best be done through the CNO. The introduction of a regulatory system for healthcare support workers is also a matter for the Government to consider again.

Commissioning

19.77 The development of commissioning as a concept has been described in *Chapter 7: Commissioning and the primary care trusts*, as has the practical reality of commissioning in Staffordshire between 2005 and 2009.

19.78 Nationally, two papers commissioned for the Darzi review, the JCI and IHI reports as previously mentioned, suggested that, as of 2008, the commissioning process was not as yet effective. In particular, they identified:

- Lack of standardisation of criteria;
- Decisions based primarily on financial considerations;
- Commissioning decisions not driven or influenced by quality;
- Lack of clinical leadership in commissioning decisions;
- Lack of accessible and reliable data for commissioning decisions;
- Lack of public engagement in commissioning process;
- Unachievable expectations;
- No real basis for selection of providers on the basis of quality;
- No tested means of assessing patient experience;
- Information was not used well in the health service.[81]

19.79 A telling commentary on the state of the NHS in 2008, produced by IHI, suggested that essential to the delivery of appropriate quality care is an understanding of the production of

80 Nicholson T128.49
81 GB/18 WS0000058889 and WS0000058893–4

health and healthcare as a system. By this, the authors meant that for care to be delivered at all there is a:

> *... mainstay collection of people, organisations, technologies, and other resources that all together, cooperating with common aim, meet the need. Almost all the excellence, or all the defects, that the patient experiences can be traced to that collection – let's call it the system of care, whether it is managed competently or chaotically.*[82]

19.80 The system now involves a multitude of agencies, clinicians, departments and so on. Taking this system to be a "health economy" providing for the needs of a defined population, the authors noted that the current direction of travel of the NHS was to try:

> *... to forge PCTs into effective actors for defining and managing the production of care as a system for health communities. Since they do not own or operate many of the components of care, PCTS can only do this through wise and effective agreements and purchasing – "World Class Commissioning", in the prevailing terms. This may be possible, but as the authors of recent explanations of "world class commissioning" see, to know* [sic]*, the job of making sense of a system of care is much, much bigger than a restrictive definition of "commissioning". A PCT capable of making care better and better over time will have to be very good at far more tasks than just purchasing well. It will have to be an "integrator" of care across many boundaries, and it will have to be able to measure and lead the improvement of care for its entire population ...*[83]

19.81 They argued that such an understanding needed a "coherent, shared framework" connected to an "agreed upon definition of the quality of care and to associated whole system measurements to be used locally", as well as nationally:

> *The agreed-upon framework would include shared, whole system aims for the health services ... such as "care without patient injuries", "continual reduction in avoidable mortality" and "increasing patient satisfaction with responsiveness".*[84]

19.82 Whilst elements of this may be apparent in the emerging practical implementation of the new reforms of commissioning, it was not apparent that such an understanding existed with clarity before World Class Commissioning was introduced.

19.83 Commissioning was introduced as a means of defining the services to be provided, and the cost of them to the public purse, without clearly providing those given the responsibility with tools and resources to do the job effectively, from the point of view of ensuring a level of

82 GB/19 WS0000058945
83 GB/19 WS0000058946
84 GB/19 WS0000058948

quality in the service. The opportunities given to PCTs to develop their methods of working were compromised by their preoccupation with reorganisation. Commissioners were provided with a vision, a national framework, and in due course a list of competences they should possess. What was lacking was a clear national set of outcome-informed, high-level, standards to be expected of the commissioned services that could be used as a basis for local development and measurement. Without these elements, commissioning was likely to remain more a matter of rhetoric than reality.

19.84 There are many tasks for commissioners to perform, but monitoring and performance-managing the quality of the service delivered should be at the heart of their work.

19.85 In its report for Lord Darzi in 2007, JCI had concluded that there were "significant flaws" in the quality oversight mechanism. Sir David Nicholson did accept that there were "elements of truth" in that conclusion.[85]

19.86 Gary Belfield, Acting Director General for Commissioning and System Management at the DH from July 2009 until September 2010, gave evidence consistent with the picture to be drawn from the JCI and IHI reports. He accepted that until the introduction of World Class Commissioning in 2007/08, "no-one had really defined what commissioning was in any detailed way".[86]

19.87 Before then, the focus had been on seeking to involve GPs in the commissioning process through what was known as Practice Based Commissioning (PBC). Through PBC, PCTs gave local GPs indicative budgets to commission services, although formally the arrangements made were between the PCT and providers. Mr Belfield said that the intention had been that GPs would be in a position to influence the quality of care through commissioning:

> *The intention was that GPs were much closer to care than the PCT, in the sense that every day in general practice about 1 million people go into general practice to see their GP or a practice nurse, and so GPs were very close to that. GPs also had strong relationships in the community and strong relationships generally with secondary care clinicians. So the view was that they were in a good position to be able to influence care, influence the shifting of care and also influence quality of care.*[87]

19.88 However, this intention was not realised. Mr Belfield accepted that GPs were not provided with sufficient data to enable them to make an informed decision on quality, but also that the expectation that GPs would undertake such a role was not made explicit:

85 Nicholson WS0000067723, para 301; DN/60 WS0000068718
86 Belfield WS0000058366, para 41
87 Belfield T124.4–5

THE CHAIRMAN: To what extent was it the intention of the policy that a GP should keep an eye on the quality as opposed to commission for it, to engage the service; do you see what I mean?

A. I do. I think it was implicit, but if I think back to – now obviously I've read the policy documents in preparing for today, we didn't make that explicit. But I think it was implicit that day in and day out the clinical community in the GP practices would be looking at quality in that sense, but it wasn't explicit.[88]

19.89 Mr Belfield also accepted that the standard form of contract issued to PCTs by the DH was much less explicit in relation to quality requirements than it was in relation to access and other national targets, and that it was recognised that PCTs in 2007/08 might well not be in a position to introduce their own quality metrics.[89]

19.90 The Rt Hon Ben Bradshaw MP, Minister of Health at the time, agreed that World Class Commissioning had been introduced in part because PCTs had previously had only very limited capacity to ascertain the quality of the services they were commissioning.[90]

19.91 The initial focus after the introduction of this concept was on the competences on which PCTs would be assessed rather than them being given the tools to assess the quality of services:

Quality was an underpinning aspect of WCC but it is fair to say that the first year of the programme focused to a greater extent on the mechanics of commissioning such as identifying health needs, procurement and performance management skills.[91]

19.92 In *World Class Commissioning: Vision*, published in December 2007, it was stated that:

World class commissioners will drive continuous improvement in the NHS. Their quest for knowledge, innovation, and best practice will result in better quality local services and significantly improved health outcomes.

By working with partners to clearly specify required quality and outcomes, and influencing provision accordingly, world class commissioners will facilitate continuous improvement in service design to better meet the needs of the local population. This will be supported by transparent and fair commissioning and decommissioning processes.

88 Belfield T124.8
89 Belfield T124.34
90 Bradshaw T116.10
91 Belfield WS0000058369, para 47

Procurement and contracting processes will ensure that agreements with providers are set out clearly and accurately. By putting in place excellent processes, commissioners can facilitate good working relationships with their providers, offering protection to service users and ensuring value for money.[92]

19.93 In June 2008, the DH published a commissioning assurance handbook.[93] This informed PCTs that they would be assessed, in terms of commissioning assurance, against up to 10 outcomes (up to eight of which could be chosen locally) using a number of specified metrics (up to three of which could also be chosen locally to reflect their strategic priorities), and against 10 competences.[94] Two such competences and one of the indicators for the assessment of each are reproduced below in Tables 1 and 2:

Table 19.1: Competency 9: Secure procurement skills that ensure robust and viable contracts[95]

Indicator	Level 1	Level 2	Level 3	Level 4
Creation of robust contracts based on outcomes	Does not meet Level 2 requirements.	All elective and non-elective acute existing contracts include clearly specified outcome and quality metrics, with a transparent arbitration process, including for ISTCs [Independent Sector Treatment Centres]. All newly negotiated contracts are based on desired outcomes (i.e. the PCT's strategic priorities) and service quality with defined improvement performance targets and improvements to patient pathways. All contracts agreed and signed by 1 April, or appropriate timescales in advance of activity commencing. Contracts have clearly defined break clauses, linking to quality variables where appropriate.	Outcome and quality targets and improvements to patient pathways are an explicit part of all negotiations and are incorporated in contracts in line with priorities in the strategic plan. The majority of existing contracts include clearly specified outcomes and quality metrics, with a transparent arbitration process, including ISTC. Services are procured and contracted for in a way that incentivises good patient experience and clinical quality. Clinical leadership are involved in review of finalisation of contracts.	All contracts include clearly specified, measurable, and practical outcomes and quality metrics, with a transparent arbitration process. Specific measurable performance improvement targets are jointly agreed. Contract incentives drive desired provider performance which results in health improvements.

92 GB/8 WS0000058677–8
93 GB/11 WS0000058704
94 GB/11 WS0000058725 and WS0000058729
95 GB/11 WS0000058791

Table 19.2: Competency 10: Effectively manage systems and work in partnership with providers to ensure contract compliance and continuous improvement in quality and outcomes and value for money[96]

Indicator	Level 1	Level 2	Level 3	Level 4
Use of performance information	Does not meet Level 2 requirements.	Data is accessible and used to monitor provider performance. Data is collected and analysed at appropriate intervals. Monthly data from providers is no more than one month old. Data is shared with providers when requested. Data collected supports key performance indicators defined in contracts.	Contract agreements support collection of performance data where national data is not available, and management control of data is clearly defined. Data is proactively discussed with providers. Data supports key performance indicators across all domains (clinical, quality, access, etc). Performance information is available for and accessible to the public where relevant. There is near real time monitoring on measures where the PCT could have influence and ensure actions to address problems as they arise.	The PCT obtains real time feedback from users on services. The PCT maintains a "live" dashboard of information on key performance indicators, and ensures it is readily available to support performance management. Data is proactively discussed with providers to drive fact-based continuous improvement in quality and outcomes. Performance information is available for and accessible to the public.

19.94 In *Chapter 7: Commissioning and the primary care trusts*, the contracts in use for the Trust have been considered: none of them is likely to have demonstrated a PCT that had reached Level 4, but then the DH would not have expected this to have been reached. Indeed, Mr Belfield told the Inquiry that if many PCTs had been expected to be at Level 4 he would have thought the benchmarks on this document to have been set too low. He and his superior, Mark Britnell, were expecting this to be a five-year "journey".[97] At the outset, he accepted, many PCTs would not be at level 3 because, among other things, they were not using data to discuss issues with providers, even over some of their activities.[98]

19.95 However, if commissioning was to be an effective tool to drive quality then it might be thought that the requirements of Level 4 were a minimum to be attained, not a maximum aspiration for the future. This suggests, firstly, that the DH was aware, or should have been aware, that quality was not at that point capable of being effectively driven by the commissioning process and, secondly, that there were no alternative means of doing so at local level at the time. In other words, the system for ensuring delivery of quality did have a significant gap in it, which it relied on front-line professionals to fill.

19.96 As indicated by the competences in the assurance handbook, the introduction of a concept such as commissioning for quality was inevitably going to take time to develop into an

96 GB/11 WS0000058792
97 Belfield T124.26
98 Belfield T124.29

effective mechanism. If the DH was unable to equip PCTs with immediate means to monitor quality effectively, it is not clear how the objective of the underlying policy was to be attained at the time. If there were effective local measures, they could and should have been shared between commissioners and providers. PCTs were in effect left to rely on the system for monitoring compliance with the Standards for Better Health by the regulator, which is considered elsewhere in this report. This was not a sufficient tool for commissioning purposes. These aspirations, if delivered locally, might have been capable of detecting the deficiencies of the Trust before the HCC investigation, but that was most unlikely to occur in the state in which commissioning found itself in 2007/08.

19.97 Matters had not improved by the time the House of Commons Health Select Committee considered the matter in 2010. The Committee's criticisms included that PCTs were passive, lacked skills, had poor analysis of data, lacked clinical knowledge, were poorly managed and lacked adequate levers to motivate providers of hospital and other services.[99]

19.98 Asked why the same problems with commissioning seemed to recur, Mr Belfield said:

> *It's certainly a recurring theme, I agree ... but that doesn't take into account the fact that over that time there have been reorganisations of PCTs ... So that's been difficult. And we haven't really, until the last two or three years, set out what we expect from these organisations in a really, truly granular way. So I think it's easy ... it's simplistic to just blame the PCTs* [on] *one level.*[100]

19.99 There are, of course, other purposes for which commissioning was introduced, which are not the subject of review by this Inquiry, but in relation to the objective of ensuring that a proper quality of care is provided it has, to date, not been a success. The Health Select Committee report and the evidence of Mr Belfield indicate that it would not be safe to confine such concerns to the PCTs that commissioned services at the Trust.

19.100 Asked if the DH were to some extent to blame for this state of affairs, Mr Belfield told the Inquiry:

> *... we've not been reticent in saying that we should have spent potentially more time helping PCTs and commissioners improve, and David Nicholson, by bringing in Mark Britnell in 2007 I think recognised that and started to move on. But I think, yes, "blame" is not the right word. But could we have done more? Absolutely, I think we could have done more.*[101]

99 *Commissioning* Fourth Report of Session 2009–10, House of Commons Health Select Committee, pages 3–6
100 Belfield T124.44
101 Belfield T124.45

19.101 In spite of the evidence that PCTs had not been given the tools for this important job, Sir David Nicholson adhered to the position that the responsibility for finding out that there was cause for concern lay with the PCTs:

> *It's a commissioner responsibility. They are there on the ground. They have the local intelligence. They have the knowledge of the organisations. The SHA itself had no mechanism for enabling that to happen. We've changed things now, in the sense that we've got more early warning systems, we're more alert to this. But at the time that simply wasn't the way it worked. We depended on those – on commissioners to give us, in a sense, the eyes and ears in the service.*[102]

19.102 Mr Belfield suggested that a reason why it may have taken so long for the DH to get around to a focus on developing means to monitor quality in commissioning was the previous make-up of the NHS Board, which now had more commissioning experience on it than before, and because commissioning was a long-term process possibly not aligned to the political cycle.[103] He thought there were two lessons for the future in relation to commissioning policy: if change is to be made it needs to be done quickly, but then allowed time to bed in rather than undertaking constant destabilising restructuring:

> *I don't think we have let commissioning changes have sufficient time to bed in, and that the drive to constantly change structure is unsettling. We need I personally think we need a longer time to settle some of these changes in. That would be the first point. The second point, which I think is of equal weight, is that if we are going to make change, we should do it much more quickly than we do. A number of the changes that we've made to commissioning over the past ten years have taken longer than I believe they should have done, which has unsettled people in the system ... It's taken people's eye off the ball from their day-to-day job, and we need to find a way, if we are going to make change, and life is all about change, but we need to make change more quickly, and then give people longer once it has changed to actually really bed in and really work. They would be the two major lessons levels, I believe. And they don't just apply to commissioning, although I think particularly there is a focus on commissioning.*[104]

19.103 The history of the implementation of the Government's policy concept of commissioning by the DH is one of a coherent theoretical concept being implemented before the structure and resources were in place to make it an effective reality. Thereafter, rhetorical expressions of aspiration were not matched by coherent practical support from the centre with regard to the monitoring and performance management of safety and quality. If commissioning has succeeded anywhere – and it probably has – this will have been likely to be due principally to local inspiration and leadership rather than the DH's contribution.

102 Nicholson T127.49
103 Belfield T124.47–48
104 Belfield T124.49–50

Regulation

19.104 The DH's approach to the healthcare system's regulation has been influenced heavily by changes in regulatory fashion across Government. Regulation was introduced in this sector in response to the concerns of the 1990s, in particular the Bristol Inquiry.

19.105 The Commission for Health Improvement (CHI), said Sir Liam Donaldson, broke new ground, as there had previously been no systems regulator and he had particularly welcomed its ability to inspect hospitals. In his view, visits of this nature, preferably unannounced, were important because it was possible to pick up the "soft" intelligence that was often missing from a perusal of documents, although he recognised there were other points of view:

> *It's about getting the look and feel of the place, perhaps informally chatting to some of the patients or relatives who might be around. Talking to some of the junior staff in private, where their bosses aren't necessarily there, and feeling confident that you've got a real feel for the place, as well as more formal set piece meetings with the management team. But I do accept that that is labour-intensive and expensive, and I do accept that there's an alternative school of thought which favours light-touch regulation and intelligent data as an alternative and are equally effective, so they claim.*[105]

19.106 The HCC was born from a direction of travel in favour of "light touch" regulation, following the Hampton Review and the work of the Better Regulation Taskforce.[106]

19.107 Sir Liam Donaldson was not only CMO during the period under review, but also, and remains today, a distinguished proponent of a patient safety culture. It is clear that he was not happy with the trends that developed in healthcare systems' regulation. Whilst he welcomed the determination of the HCC to obtain better information and the drill down into organisations using it, he thought it was unfortunate that, through no fault of its own, the HCC was not given the ability and the resources to do more by way of inspection and visiting: "I do feel it's very, very difficult to get a proper understanding of the service without some degree of site visiting."

19.108 In an ideal world he would advocate visiting every site, and he warned that risk-based methods depended on the reliability of the risk assessment: "Risk-based inspection isn't a suitable alternative because the methods for predicting risk are not reliable at the moment. If they were, then you could argue for it."[107]

105 Donaldson T122.85; see also Donaldson WS0000070126, para 72
106 Philip Hampton (March 2005): *Reducing Administrative Burdens: Effective inspection and enforcement* www.bis.gov.uk/files/file22988.pdf; and *Less is More* (March 2005) Better Regulation Task Force
107 Donaldson T122.86–87

19.109 He was concerned at the time about the introduction of risk-based inspections as he did not consider there was evidence to support the reliability of the methods available.[108] Therefore, he felt that there was more reliance on self-assessment than was "ideal".[109]

19.110 Sir Liam put these points at the time, but the countervailing pressures were too great:

> *I always put my points of view in debates like this, and I always tried to put them as forcefully as I could. But there was a very strong countervailing force coming particularly from the Treasury, which eventually led to the merger of the two regulators, and there was a better regulation task force, which covered the whole of Government. So there were considerable forces marshalled on the other side of the battle line on this one, and it was one that I think certainly I was unlikely to win.*[110]

19.111 He considered that it was important that standards involved both processes and outcomes. In particular, he thought that it was impossible to relate remotely the detail of much of healthcare provision in which the standards had to be devised locally and be referable to local information:

> *... the thrust, I think, has to be on two levels in overseeing this. One is to generally concentrate on outcomes. So in cancer, you would be looking at survival rates of things of that sort. And then the other thing is to have some sort of standard that generally quality assures the sort of data that people are using. So you are assuring their system, if you like, rather than the detailed items of data that they're collecting along the way to trying to improve those survival rates.*
>
> *Q. What that seems to suggest is that you need somebody keeping an eye on both the processes and the outcomes?*
>
> *A. Yes.*[111]

19.112 Sir Liam did not accept that self-assessment was a weakness in regulation, so long as it was regarded as a first step:

> *... the trouble is with these situations that they always end up in black and white arguments. Nearly everything is shades of grey. And you can say that, in one way of looking at it, self-assessment is a bad thing and should never be used because people can cover up their problems. On the other hand, you can look at self-assessment as an extremely positive thing as a first stage, then, to an inspection or a review by the regulator ... And I think the best of them have a system of self-assessment where the*

108 Donaldson T122. 88–89
109 Donaldson T122.90
110 Donaldson T122.89–90
111 Donaldson T122.31

organisation has actually had to sweat out the information and learn and really challenges itself to how good it is, and then the regulator comes in, and then you've got a win-win, you've got an organisation that is striving to show its amongst the best and then correcting things where it itself realises it's not, and then the regulator adding value with its own judgement or endorsement of what's been said. But to come up with something which allows an organisation to pass through purely on the basis of a one word like that, is completely inadequate, in my opinion and in my knowledge of such systems working elsewhere.[112]

19.113 With regard to the merger of three regulators, including the HCC, into the CQC, Sir Liam Donaldson told the Inquiry that he had harboured concerns about this:

I think this was a Treasury decision as part of the goal to reduce the number of public regulators per se and reinforce the drive towards "light-touch" regulation.[113]

19.114 Sir Liam was concerned about two issues: whether the new organisation was allocated sufficient resources, and whether it was too big. He understood why, with a different job to do with regulation of compliance of standards for registration, the CQC was not given the role of supporting improvements. He further commented on the challenges of the latter approach to regulation:

On the philosophical – on the policy point, traditionally, regulators in healthcare around the world have started by being quality assurance organisations and have moved over time to becoming quality improving organisations. That does bring its own dangers, because when you work with an organisation to try and help it improve quality, then your sympathies are probably likely to lie with them because you've been working with them. It is more difficult then to make an independent judgement if you think that their standards are not that good.[114]

19.115 The decision to merge the functions of the HCC, the Commission for Social Care Inspection (CSCI) and, a little later, the Mental Health Act Commission into what would become the CQC was taken within a year of the commencement of the HCC.[115] This was informed by the clear trend in regulatory reform following the commitment of the Chancellor of the Exchequer in 2005 to reduce the regulatory burden whilst continuing to ensure high standards. He proposed that unnecessary inspections should be avoided and risk-based regulation be practised. He announced that 35 "inspection bodies" would be reduced to nine, with a single body for

112 Donaldson T122.79–80
113 Donaldson T122.118; Donaldson WS0000070145, para 123
114 Donaldson T122.122
115 Sir Hugh Taylor WS0000061937, para 34.4; O'Brien WS0000059311, para 15

social care services and health.[116] This remained the Government's policy throughout the period under review.[117]

19.116 Part of the intention of the Government was to reduce the cost to the Exchequer in respect of regulatory activity. In health, this meant a target to reduce the combined costs of the HCC and the CSCI by between 37% and 41%.[118] In the financial year 2009/10, the CQC was operating on a budget of £164 million compared with the combined budget of the two organisations in 2005/06 of £240 million.[119] Sir Liam Donaldson told the Inquiry he was concerned at the time of the capacity of the CQC to do its job on more limited resources, and whether the task was too complex for one organisation.[120] Sir Ian Kennedy had expressed his concern about this.[121] Una O'Brien's recollection was that within the DH it was accepted that it was a "done deal" that regulators would be rationalised, but that the aim would be to do so in an "intelligent" manner to allow for resources to be used "discerningly" where they were most needed.[122] It was to this end that the Essential Standards and the provision of direct enforcement powers were created. In her view, these standards started with the experience of patients of the outcome of care and worked back to what might be the cause of deficiencies, instead of looking down through an organisation from its headquarters:

> *My own experience, from the time that I was a director of clinical governance, is that it's all too easy to say that systems are in place and working from the point of view of, have you got the right documents? Do you have the right meetings, and so on? And not to actually achieve the outcomes that are needed for patients and people. So what we were endeavouring to do with this approach was to turn things around the other way.*[123]

19.117 This approach marked a sea change from the approach given to the HCC: the CQC's mission would be to regulate essential standards, whereas the HCC's purpose was to encourage improvement. Una O'Brien explained that following Lord Darzi's vision, the role of improvement was to come from within the clinical community, whilst the Essential Standards were to be a "floor" below which no provider should fall.[124] In spite of including among the

116 *Hansard*, 16 March 2005, col 261–262; O'Brien WS0000059311, para 14
117 O'Brien T125.7
118 UOB/4 WS0000059400, paras 1 and 3
119 CQC00050000108, *Board Meeting: White Paper – Consultation Responses* (15 September 2007)
120 Donaldson WS0000070145, para 123
121 Donaldson T122.118–119
122 O'Brien T125.14
123 O'Brien T125.31
124 O'Brien WS0000059317–318, para 36

CQC's statutory objectives the encouragement of improvement of the health service, Una O'Brien said that:

> *... it is not the role of the Care Quality Commission to be out there at the frontiers of improving care, raising things to the next new standard that's becoming possible, because we need to actually police the essential levels of safety and quality, and by giving it a very specific focus to do that, the judgement has been that there is a greater likelihood of success by giving it that, rather than having a comprehensive range of actions, which you might say are a blurring of regulation and performance management.*[125]

19.118 The DH was alive to the challenges facing both the HCC and the CQC in dealing with the restructuring, and as the sponsor department was involved in seeking to make the transition effective. The evidence summarised in *Chapter 9: Regulation: the Healthcare Commission*, shows that the morale of HCC staff was inevitably hit during the lead-in to the merger, making its work more challenging. Equally, the CQC faced problems because of difficulties in engaging in advance with HCC staff. In a note for the Rt Hon Ben Bradshaw MP as Minister, in February 2009, Una O'Brien noted that:

> *Access to future CQC staff has been extremely low during the establishment period as the existing commissions complete their work programmes. The impact will be that in the first quarter of 2009 to 10 CQC will be less formed and less well organised than it could have been.*[126]

19.119 A further issue was:

> *The run-on costs of the current commissions as of 31 March is independently assessed as being close to £190m, not the anticipated £165m expected from the BRE Targets. This has resulted in CQC's establishment task being made much harder including the potential for further reorganisation to strip out much of the gap between the run-on costs and the BRE target. Some of this reorganisation has had to be left to 2009/10 because of the workload* [of] *the current commissions in their remaining period of 2008/09. This will leave CQC facing a further unsettling period of downsizing and reorganisation during 2009/10 post establishment and not focusing as much on the job in hand as had been intended.*[127]

19.120 Una O'Brien told the Inquiry that additional resources had been given to the CQC when its Chair had asked for them.[128]

125 O'Brien T125.28–29
126 O'Brien T125.49
127 UOB/15 WS0000059675; O'Brien T125.50–51
128 O'Brien T125.58

19.121 Since then there has been recognition of the challenges facing the CQC. The DH's performance and capability review in 2012 recognised that:

> *With hindsight, both the Department and CQC underestimated the scale of the task of establishing a new regulator, bringing a new regulatory system into place and managing expectations of what CQC's role would be. Even so, CQC could have done more to manage operational risks.*[129]

19.122 As a result, the CQC is in the course of reviewing its strategy.

Relations between organisations

19.123 It has been clearly recognised by the NQB in its report on early warning systems in the NHS how vital clear lines of communication and cooperation are between organisations in the system.[130] A duty to cooperate is included in several statutes, not least the Health and Social Care Act 2012. In that Act:[131]

- There is a provision requiring Monitor to cooperate with the CQC, including a requirement that there be available a single application form for registration by the CQC and the grant of a licence by Monitor;
- The pre-existing statutory duty imposed on the CQC to cooperate with Monitor was reiterated with parallel specific requirements being enacted;
- A duty was imposed on the CQC, Monitor, the NHS Commissioning Board, NICE, the Health and Social Care Information Centre, special health authorities and any other body prescribed by the Secretary of State to cooperate with each other;
- In the event of the Secretary of State being of the opinion that a body subject to a relevant duty of cooperation has breached or is breaching that duty, or is at significant risk of breaching it, he is empowered to serve a notice of his opinion, and, if satisfied that the breach is having a detrimental effect on the performance of the NHS, he may prohibit a body from exercising specified functions or exercising its functions in a specified manner.

19.124 It is of concern that such explicit provisions have been justifiably thought necessary to regulate the behaviour of regulators and other health service organisations. As is apparent from the relevant chapters in this report, Monitor authorised the Trust as a FT in ignorance of the concerns harboured by the HCC at the time, as a result of a failure of effective implementation of the memorandum of understanding between them. Underlying this was a more deep-seated fracture of the relationship informed by Monitor's guarding of its independence.

129 *Performance and Capability Review: Care Quality Commission* (February 2012), DH
130 *Review of Early Warning Systems in the NHS – acute and community services* (February 2010), National Quality Board; www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_113020
131 Health and Social Care Act 2012, sections 288–291

19.125 While the HCC and Monitor were independent of the DH, it had been apparent to the DH for some time that there were difficulties in the relationships between regulatory bodies:

- A memorandum from Ms Chris Outram to the Minister of State for Reform (Lord Warner) dated 10 February 2006, dealing with whether Monitor and the quality regulator should remain separate, stated:

 It does nothing immediately to eliminate differences and tensions between Monitor and the HC, and exposes the difficulties in balancing quality improvements with financial constraints. If we pursue this option, we would suggest that action needs to be taken to manage the debilitating relationship between these two bodies, potentially through a memorandum of understanding to back up the existing statutory duty for the two bodies to cooperate.[132]

- In June 2006, a DH official emailed another about the ongoing consideration of structural change to the existing regulatory bodies. He wrote: I'm struck by the problems we've had in getting HC, CSCI, Monitor and AC to work closely together when the primary legislation already expressly requires cooperation ..."[133]
- Sir Andrew Cash, then the DH's Director General of Provider Development, produced a paper for Sir David Nicholson and Sir Hugh Taylor on 9 May 2007 discussing the future direction of Monitor.[134] It included the following phrases:

 The world is moving on and we should take a view on whether Monitor's fiercely guarded independence should be maintained at a time when the change in the regulatory climate suggests we might need to redefine the boundaries between operational independence for NHS providers and where we have levers for central influence.[135]

 We have had a clear Ministerial steer that [CQC] *should have the gate-keeping remit over other inspection and regulation bodies operating in the health and adult social care sector – including Monitor. This will require Monitor to establish genuine cooperation with* [CQC]*, as well as SHAs.*[136]

 We need to be driven by how we want Monitor to perform. I see this as being ... a much greater acceptance of the need to cooperate with [CQC].[137]

132 UOB/4, WS0000059405, para 21
133 GW/15, WS0000061026
134 AC/23, WS0000061920
135 AC/23, WS0000061922, para 3
136 AC/23, WS0000061923, para 4(iii)
137 AC/23, WS0000061923, para 5

19.126 In evidence, Sir Andrew qualified the apparent implications of his paper by stating that the note did not necessarily reflect a concern that Monitor was not cooperating properly with the HCC; he was just pointing out the need for cooperation in the future.[138]

19.127 A memorandum by David Flory and Una O'Brien to the Secretary of State and Minister of State for Health dated 22 June 2009[139] stated:

> *Monitor ... was intended as a light touch regulator but is sometimes perceived to have evolved into a lobbyist for FTs, or even their de facto HQ.*[140]
>
> *Our sense is that the Mid Staffs issue is in part about relationships – the position could well have been quite different if Monitor had been more willing to work with other parts of the system.*[141]

19.128 There was a suggestion that the failure of the system in this regard may not have received a complete public acknowledgment by the DH. In an email of 14 January 2010 (commenting on the content of the draft NQB report on early warning systems within the NHS), Ms Jo Lenaghan wrote:

> *There is no 'hands up' moment where we as a system admit that we did not work together as the public might have expected us to. I think it would be possible to do this in a way that was honest without over-doing it, i.e. it was a new system in transition, there was a lack of clarity of roles, and some people were more worried about policing their boundaries rather than working together.*[142]

19.129 However, in her oral evidence to the Inquiry, Una O'Brien, as the current Permanent Secretary, acknowledged the failure:

> *... there were strengths and weaknesses to that relationship. I certainly don't recognise that term "debilitating" at all. I think we can now see and we've learnt from experience of what's happened that without a shadow of a doubt there should have been much, much better exchange of information between those bodies. There should have been stronger cooperation and collaboration than there was, and the Department itself play a stronger role in providing sort of stewardship and oversight of those relationships. So we can now understand that. As you will appreciate, I was not personally directly involved in the relationships with those organisations at that time, so I find it quite difficult to comment honestly on that, other than to reflect back to you what I know I've heard people say about it ...*

138 Sir Andrew Cash T119.111
139 UOB/31, WS0000060069
140 UOB/31, WS00000600672, para 12
141 UOB/31, WS0000060078, para 41
142 UOB/25, WS0000059947

– I think it was an era where strong leaders came in and asserted their respective roles and defined their territory. And I think that we were probably slow off the pace in forcing through what eventually came, which were the memoranda of understanding and the stronger stewardship of the relationship between the organisations.[143]

19.130 The Rt Hon Andy Burnham MP attributed the failure of communication to "personalities":

Whilst I do find it staggering that the HCC and Monitor did not communicate about Mid Staffs, I put this down to personalities within the organisations rather than any deficiency within the policy they were following. I believe there was too much posturing around that period in relation to organisational pride ... Monitor was strongly asserting its independence ...[144]

19.131 Whether the issue was one of "personalities" or structure of the system or competence, the DH appears to have adopted the passive role of spectator.

Pressure on strategic health authorities to accelerate the foundation trust process

19.132 A suggestion has been made that the DH placed pressure on other organisations for political reasons.

19.133 There was a strong politically driven will to accelerate the process of converting as many trusts as possible into FTs, as described in *Chapter 4: The foundation trust authorisation process*. That, the evidence shows, led to an implementation of the policy which had the effect of lowering the threshold that aspiring FTs had to cross to be considered for support by the DH to be put forward for assessment by Monitor. There was, however, no conscious decision that this should be the case: the deficiency in the process leading to this policy change was that insufficient thought was given to the consequences for Monitor's assessment methods. It continued to rely on an assumption that the routine standards assessment was a valid measure of quality performance, when it had become insufficient for this purpose. Senior officials from the DH deny that they were influenced by political pressure to push trusts through the FT pipeline regardless of their quality and whether they were ready, and there is no evidence on which to conclude that to have been the case.[145]

143 O'Brien T125.94–95
144 Burnham WS0000003426, para 92
145 Cash T119.22 and T119.27; Brown T118.32–3, T118.69 and T118.115–6

Change in regulatory techniques

19.134 The suggestion has been made that there was a deliberate DH decision to change the regulatory technique from one based on self-assessment (the Annual Health Check) supported by inspection by the HCC, to a form of continuous compliance monitoring in order to avoid the embarrassment of another Mid Staffordshire-style report. This is not the case.

19.135 There were significant deficiencies in the system, of which the HCC was a part. However, the measure that was effective in discovering the deficiencies at the Trust was a full-scale investigation rather than an inspection. This measure had its own disadvantages in the time taken to complete it and before remedial action could be taken. The evidence shows that there was a move away from physical inspections once the CQC had assumed its regulatory responsibilities; this was unfortunate, but this was not the result of Government intent, rather implementation of its remit by the regulator when under severe pressure to register large numbers of organisations in a short period of time. In fact, the direction taken by the CQC has since changed, following a series of inspections directed by the Secretary of State, and it is evident that more physical inspections are now taking place. The suggestion of a change in policy being introduced for an ulterior motive is without foundation.

Intervention in the Healthcare Commission investigation findings

19.136 It has been suggested that the DH interfered in the content of the HCC's investigation report of the Trust. The evidence concerning the discussion between DH Ministers and officials and the HCC about mortality figures has been considered in *Chapter 9: Regulation: the Healthcare Commission*. It is clear that the decision to remove the figures was that of the HCC acting in accordance with its independent judgement. There was a legitimate discussion about them with the DH, but at no time was any improper influence brought to bear. The DH was entitled to comment on the draft report as it had been invited to do so. No one who has heard the evidence of Sir Ian Kennedy or considered his record of service in the regulation of healthcare for the benefit of patients could reasonably be persuaded that he acted with anything other than the most rigorous independence.

Department of Health interaction with the Trust

Complaints

19.137 The DH is not a regulator and has no formal part to play in the NHS complaints system. Nonetheless, it inevitably receives complaints that patients and MPs wish to draw to the attention of the Secretary of State. The DH received 119 letters of complaint about the Trust during the period under review. It conducted no analysis of them at the time but handed them on to the Trust. Had it reviewed them then as it did in the aftermath of the Stafford scandal, it would have found many concerns raised that were to be confirmed in the HCC

report. It did not pass on any information about these complaints to the West Midlands Strategic Health Authority (WMSHA).[146]

19.138 The DH accepts that its system in relation to complaints was inadequate. Una O'Brien told the Inquiry that she had reviewed the system and had established a system for classifying and processing complaints received by the DH. Now, if in the judgement of a manager a complaint requires an immediate intervention to safeguard an individual, he/she is required to call the appropriate authority and request action. Concerns about the quality of care will be passed to the CQC and serious complaints also referred to the DH's NHS Business Unit which could seek action from an SHA or Monitor as appropriate.[147]

Foundation trust application

19.139 The DH's development of policy in relation to FTs and its involvement in the Trust's application is fully considered in *Chapter 4: The foundation trust authorisation process*.

19.140 The story is one of the implementation of a policy being accelerated and the thresholds being lowered along with a focus on financial governance rather than any effective focus on the standard of service being delivered. Even within the looser criteria in existence by the time the Trust made its second application, there were doubts that were ignored to allow the Trust to go forward for assessment by Monitor. Those doubts were not shared with Monitor. The system as a whole did not focus on the warning signs that would have indicated the serious deficiencies at the Trust.

Healthcare Associated Infection Team

19.141 Dame Christine Beasley described to the Inquiry how she had established the Healthcare Associated Infection (HCAI) and Cleanliness Improvement Plan in 2005, to build on previous work to support the NHS achieve improvements in infection prevention and control. The programme had four goals:

- To implement a plan to deliver sustainable reductions in HCAI and improve patient and public confidence;
- To improve clinical and managerial practice;
- To provide effective performance management systems;
- To support challenged organisations by promoting innovation and good practice.[148]

19.142 A core part of the programme was the HCAI Improvement Team, which was established to provide direct support to individual NHS organisations in putting in place practices and

146 Cumming WS0000016667, para 39; Cumming WS0000016689, para 98
147 O'Brien WS0000059350–353, paras 128–132; O'Brien T125.119–121
148 Beasley WS0000051835–6, para 136

systems to reduce HCAIs. The team was made up of NHS managers and clinicians with experience in service improvement and change management, and it had no direct performance management function.[149] As Dame Christine explained:

> *The success of the Improvement Team relied on trusts being prepared to be open and honest about their problems and work constructively with the improvement team to improve their performance. Had the improvement team been seen to be part of the NHS inspection or performance management regime, I believe fewer trusts would have been as prepared to engage with the Programme ...*
>
> *... That said if the Improvement Team uncovered issues of serious concern these could be swiftly escalated to the SHA, Monitor or the HCC as appropriate. The Improvement Team also met regularly with the DH's NHS performance team (initially the Recovery Support Unit, then the Performance Delivery Team) to review performance data and share soft intelligence. The Improvement Team highlighted the trust* [sic] *with infection rates that were high in comparison to other similar hospitals which allowed the performance team to speak to the relevant SHAs regarding any remedial action that may be needed.*[150]

19.143 This team visited the Trust on 17 October 2007 and three times for follow-up in March 2008. It visited many of the wards that were to be the subject of criticism in the HCC report of the investigation, which had by then just started. The HCAI report was that there had been good progress and signs of good compliance with Trust policies on HCAI prevention, whilst there remained scope for improvement. Dame Christine Beasley told the Inquiry that questioning of the team indicated that they had found no cause for major concern.

19.144 One issue the team did not pick up on was the combination of vascular and colorectal patients in one ward as part of the clinical floors programme. It was clear from Dame Christine's evidence that this was something she would have reacted to with horror if she had seen it. She could only speculate that the team had not been looking at the nature of the patients in the ward (although this must have been clear from its title). The report did not identify the issues raised later by the Health Protection Agency (HPA) about the Trust's engagement with HPA advice in its response to *C. difficile* outbreaks in 2008.[151] Apparently, the HCAI team had been focusing on MRSA, not *C. difficile*.[152]

Department of Health reaction to the Healthcare Commission investigation

19.145 The DH's approach to the HCC investigation was to rely on the regulator to advise whether special measures were required rather than to seek to form its own independent judgement of the state of affairs as information about the investigation was received.

149 Beasley WS0000051836, para 137
150 Beasley WS0000051837–8, paras 139 and 141
151 See *Chapter 16: The Health Protection Agency*
152 Beasley T117.135–9

19.146 The DH heard through various sources about the impending announcement of the HCC investigation shortly before it was made.[153] On 17 March 2008, a 15-page briefing note was submitted to the Secretary of State and the Minister of State for Health and widely circulated in the DH. The note struck a reassuring tone:[154]

- It noted that the Trust was fully cooperating with the HCC which was: "keen to stress that the investigation was precautionary".[155]
- Whilst it noted that the Trust was an outlier on a number of sources: Hospital Episode Statistics, Healthcare Resource Grouping (HRG), and Hospital Standardised Mortality Ratios (HSMRs), the HCC had pointed out that "every statistical range will have someone coming first, someone coming last, and no assumptions can be made at this time about patient safety in Mid Staffs".[156]
- The "very worst case scenario" was said to involve "100+ premature deaths":

 ... but the HCC is very anxious to stress that this is not a given. The HCC investigation will establish whether there has been a real problem in patient care. If so how big the effect, and whether the trust is maintaining appropriate standards in the management, provision and quality of its services.[157]

- The intended press statement of the HCC was enclosed. In this, Nigel Ellis, Head of Investigations, was quoted as saying: "An apparently high rate of mortality does not necessarily mean there are problems with safety. It may be that there are other factors such as the way the information about patients is recorded."[158]

19.147 By way of comment, if no assumptions could be made that patients were safe, it might be thought that this was a matter for concern. The briefing contained other information that was likely to undermine confidence that all was well at this Trust in terms of patient safety:

- It was reported that although "substantial work" by the Trust had produced evidence that the overall mortality rates were not "significantly worse than anywhere else", recent analysis by the HCC and Dr Foster had again "set the alarm bells ringing". Recent alerts had pointed to a cluster of poor results in A&E and older people. This data was generally considered to be more specific and robust than the composite HSMR data.[159]

153 Flory WS0000066626, para 41
154 DF/13 WS0000066934
155 DF/13 WS0000066935, para 1
156 DF/13 WS0000066935, para 2
157 DF/13 WS0000066935, para 3
158 DF/13 WS0000066936, para 8
159 DF/13 WS0000066936, paras 6 and 10

- It was suggested that there was no indication that Monitor's decision to authorise the Trust was weak or wrong. However, the note warned that there might be:

 ... suggestions that while the SHA and Monitor looked at historic data and signs of activity and a recent improvement in mortality rates, Monitor might have waited to see if the improvement was sustained prior to awarding FT status.[160]

- The note stated that there were reported concerns about the standards of care at ward level, raised, for instance, by Julie Bailey and her group.[161]
- It was observed that it was now for Monitor to ensure that the Trust met the requirements for effective governance:

 For example Monitor will need to consider and respond to a possible worst case scenario where the HCC finds that actual mortality rates have been disproportionately high (i.e. not just poor data collection) in emergency and non elective procedures across specialisms, especially older patients. This could lead to consequent allegations that the FT had prioritised targets and income earning elective procedures above others, ie clinical need was deprioritised.[162]

19.148 A "reactive" media statement was prepared which briefly confirmed that the DH was aware of the investigation and that the Trust and Monitor would be working with the HCC and considering any recommendations made. The statement started: "Patient safety in the NHS is paramount."[163]

19.149 Enclosed with the briefing was a press statement by Martin Yeates which sought to reassure the public that safety was the Trust's top priority and that: "I would like to repeat the Healthcare Commission's statement that if our services were unsafe, they would have taken action already."[164]

19.150 Therefore, Ministers were in effect being asked to do no more than agree a line to take in the event of media enquiries and to await events. The tone of the briefing was to predict matters that might give cause for criticism in the future, but that action could be left to the regulators and the Trust itself. It was not clear that an assumption that there was a reassuring explanation for the mortality figures would be justified, but overall the approach advocated was to assume that there was no cause for concern about patient safety until the DH was advised to the contrary. It was clear from the press statements of the HCC, Monitor and the Trust that this was an approach shared throughout the system.

160 DF/13 WS0000066937, para 15
161 DF/13 WS0000066939, para 18
162 DF/13 WS0000066938, para 15
163 DF/13 WS0000066942
164 DF/13 WS0000066946

19.151 When Sir David Nicholson received this note, he asked an official to ensure that the PCT, as lead commissioner, was "fully engaged" in resolving any problems.[165] He told the Inquiry that with the benefit of hindsight:

> *... we can see that the various regulatory and management bodies were too readily assured that the issues identified were not ones that indicated concerns about patient care at the Trust ... There was far too much focus on debating the validity of statistics and insufficient attention to addressing the issues of poor care which we now know to have been endemic ... There was also a false sense that problems with patient care, if they had existed at all, were not ongoing or something about which patients should be overly concerned.*[166]

19.152 On 12 May, Sir David Nicholson's office received a briefing note[167] in advance of a meeting with the HCC on 14 May 2008. It informed him that the HCC had undertaken three visits to the Trust which had "uncovered possible issues with the management of care pathways (undermining the standard of nursing care)".

19.153 The note suggested that the HCC be asked for an update on findings and timelines and "specifically for advice on where immediate operational improvements might be required".

19.154 The observation was also made that:

> *In the past the HC* [C] *has been reluctant to make suggestions or recommendations to DH at a senior level until its investigations are complete. Investigators do talk off the record to DH officials in the relevant SHA, but it can be difficult to turn this low level contact into immediate managerial action.*[168]

19.155 It was suggested that the short-term public interest in the HCC prompting senior managers in the DH or the SHA to consider action did not have to conflict with the longer-term public interest in the HCC holding the NHS publicly to account.

19.156 At the meeting on 14 May between Sir David, David Flory (Director General of Finance, Performance and Operations), Sir Ian Kennedy (Chair of the HCC) and Anna Walker (Chief Executive of the HCC), no suggestion appears to have been made that there had been any substantial change in circumstances since the HCC's original announcement.[169] It was agreed that the HCC would provide regular updates.[170] Anna Walker's report of the meeting

165 Nicholson WS0000067698, para 218
166 Nicholson WS0000067699, para 221
167 BK/13 WS0000065525
168 BK/13 WS0000065526, para 1
169 Nicholson WS000006770, para 224
170 DN/41 WS0000068491, DH meeting note

recorded that she had told the DH that the HCC had received an "overwhelming" response from the public on quality of care issues. Sir David was reported to have warned about:

> *... a local campaign group in existence against Mid Staffordshire for some time. Clearly patients needed to express their views but he hoped the Healthcare Commission would remain alive to something which was simply lobbying or a campaign as* [opposed] *to widespread concern.*[171]

19.157 Sir David told the Inquiry that he could not recollect this comment, but that whatever he said he would not have intended to suggest that the HCC should not take notice of what local people had to say or to influence the investigation.[172] In any event, Anna Walker told the Inquiry that she had not felt that the HCC was in any way being "warned off" undertaking its investigation, which it would not have allowed itself to be in any event.[173]

19.158 On the occurrence of this sort of meeting, Anna Walker was adamant that it was not wrong for an investigation to be discussed with the DH in this way:

> *I would be concerned if you were to be drawing conclusions that, although this relationship – or perhaps "partnership" is not the right word, but working alongside those you're regulating was wrong in all circumstances, because if improvement is what one's seeking to achieve, the regulator, with hopefully their knowledge of what is good and their knowledge of what others are achieving, can actually help an organisation with the right attitude to improve. And to take the relationship between the regulated and the regulator, such that that couldn't happen I think something quite significant would be lost. On the other hand, I do recognise that there is separate functions to carry out, and there is this question, whatever we – where we were clear that we would stand up and be counted as and when we needed to, as indeed we did, there are also issues about perception.*[174]

19.159 The HCC letter of 23 May 2008 to the Trust outlining its serious concerns about A&E was copied to the DH.[175] It prompted a director at the DH to arrange for it to be forwarded to the Chief Executive of WMSHA, Cynthia Bower, with a message that the HCC would consider the Trust's response to the letter inadequate "if it did not include plans to add a senior clinical presence in the immediate future to begin to address the position".[176]

171 DN/42 WS0000098498
172 Nicholson T127.183–184
173 Walker T83.145
174 Walker T83.147–148
175 Flory WS(45) WS0000066627; Flory DF/15 WS0000066952
176 Flory WS(45) WS0000066627; DF/16 WS0000066958

19.160 David Flory, who could not recall whether he had seen the letter immediately,[177] explained that although the WMSHA would not have had formal powers in relation to an FT, he would have expected there to be informal dialogue with the Trust, and through that, be in a position to resolve some of the issues.[178] He accepted that what the DH or the WMSHA could do was limited as they were no longer performance managers of the Trust; the only route of intervention would have been via the PCT and its commissioning relationship with the Trust. He thought that particular gap had been remedied by the powers given to the CQC to intervene directly.[179] In retrospect:

> *When I look back at this now, if I received a letter like this tomorrow, on another trust, I would engage very quickly with the medical and nursing directorate, the Department of Health, which I didn't do at the receipt of this letter, and take further advice from there.*[180]

19.161 Asked why he would not at the time have wanted clinical advice about the medical staffing issues raised in the HCC letter, he told the Inquiry that normally the primary means of communication by the HCC to the DH was via the DH's NHS Medical Directorate, and he would therefore have assumed he had not been the only person in the DH to have seen the letter.[181]

19.162 Indeed, he could not have been the only person to see it. The letter, or the details to be derived from it, reached the Rt Hon Ben Bradshaw MP, Minister of Health. It appears from his evidence that he would have noted that the letter raised serious concerns but that the HCC had required specific actions to be taken by the Trust. He would have considered the role of the DH, the SHA and the PCT at the time was to ensure that the recommendations were implemented, and he would not have expected any direct intervention by Monitor:

> *I think the concern of me as a Minister would be to ensure that the hospital – to assure ourselves that the hospital, the SHA, Monitor, whoever were involved in whichever case, were cooperating with the Healthcare Commission investigation and implementing their recommendations. So I think if you're asking me … should Monitor have been going in and stepping on the Healthcare Commission's toes, no, I don't mean that. I think the Healthcare Commission were on the ground with a very capable team uncovering this stuff. They had a clear picture of what needed to be done at the hospital, and were making recommendations to the hospital. I think … our main concern was that the hospital was responding appropriately.*[182]

177 Flory T121.119
178 Flory T121.114
179 Flory T121.116
180 Flory T121.120
181 Flory T121.120–121
182 Bradshaw T116.119–120

19.163 The HCC letter was not seen at the time by Professor Sir Bruce Keogh, NHS Medical Director[183] or Sir David Nicholson.[184] They both gave the impression that a different course of action might have been followed had they seen it. Sir Bruce agreed that "without a shadow of a doubt" it raised serious issues about what was happening at the Trust. He had asked himself why he had not seen it at the time and concluded that it was because the letter had already been sent to Monitor, the South Staffordshire PCT (SSPCT) and the WMSHA, meaning that all relevant organisations had been informed of the position. Had he seen the letter he would have pursued it:

> *... as I read this, I found myself thinking I would have liked to have had a face-to-face conversation with Ian Kennedy and Anna Walker, and it's easy to say that sitting in front of the inquiry, but I like to think that I would have done it anyway, because it does pose questions as to whether enough was being done quickly enough.*[185]

19.164 However, he told the Inquiry that the DH had at several meetings asked the HCC whether there was any need for it to become involved and that the answer was always "no".[186]

19.165 Sir David Nicholson was blunt: "Clearly whoever read it didn't understand the scale and nature of what was being said in it."[187]

19.166 However, he told the Inquiry that if he had seen the letter at the time, the action he would have taken would have been limited:

> *I would have assumed that people were taking action in relation to that and putting it right, otherwise someone would have said to me, "They're not taking action, is there any help we can give to make that a reality?" Or the Healthcare Commission would take whatever powers it needed to do with Monitor to ensure that intervention took place.*[188]
>
> *...*
>
> *THE CHAIRMAN: If I may say so, passing a letter from one desk to another is not action.*
>
> *A. I don't disagree with that. Absolutely right. And in a sense if I'd have seen it I would have wanted to know what the action was that people were taking. But I didn't see it so I didn't do that.*

183 Keogh T123.43
184 Nicholson T127.185
185 Keogh T123.44
186 Keogh T123.34
187 Nicholson T127.193–194
188 Nicholson T127.186–187

THE CHAIRMAN: The context of the letter is still that this is only months after this trust has been authorised as a foundation trust. Would that not have started ringing some alarm bells about the wisdom of relying on other organisations to ensure patient safety?

A. Well, it didn't ring those alarm bells.[189]

19.167 It is clear that the HCC letter did not have the impact that the totality of the eventual HCC report had. Sir Hugh Taylor, who also did not see the letter at the time, told the Inquiry that there was nothing in it, or subsequent letters, that would have prepared him or Ministers for the full impact of the report.[190]

19.168 The DH also received copies of the HCC's letters of 7 July and 15 October 2008, also described in *Chapter 9: Regulation: the Healthcare Commission*. Mr Flory characterised these communications as having been sent to the DH for information only as they were also sent to the SSPCT, the WMSHA and Monitor.[191]

19.169 Mr Flory told the Inquiry that after the meeting of 14 May, he met Anna Walker on a number of occasions. He could not recollect "any expressions of concern about the investigation ... Indeed at no time prior to the issue of the draft report was I made aware that the HCC had identified that serious concerns were emerging".[192]

19.170 Indeed, he considered that the updates were reassuring. He cited the HCC press release of 25 September 2008, which stated that the Trust "had responded positively to concerns that the Commission had raised about the safety of patients in [the Trust's Accident and Emergency Department]."[193]

19.171 He expected that if the HCC had immediate concerns about patient safety they would have recommended the taking of special measures.[194]

19.172 The Rt Hon Ben Bradshaw MP, then Minister of Health, told the Inquiry that he met Anna Walker on 28 July 2008 and was assured by her that the situation at the Trust was not as serious as had been the case at Maidstone and Tunbridge Wells and that in her view the Trust and the HCC were working well together to resolve the issues. He told the Inquiry that at every stage he was reassured by the HCC that the hospital was responding and doing what the HCC required.[195] He considered that this reassurance was reinforced by the press release referred to above.[196] Having read the HCC report he considered that the advice he was given

189 Nicholson T127.187
190 Taylor WS0000061942, para 48
191 Flory WS000066627–628, paras 45–46; DF/17 WS0000066960; DF/18 WS0000066963
192 Flory WS0000066628, para 47
193 Flory WS0000066628, para 47
194 Flory WS0000066629, para 49
195 Bradshaw T116.116
196 Bradshaw WS0000030267, para 71

was wrong.[197] The reference to Maidstone and Tunbridge Wells had particular resonance both for Mr Bradshaw and the then Secretary of State, the Rt Hon Alan Johnson MP, because following the report on that case Mr Johnson had expressed his "exasperation" at not having received warning about it. This had not left Ministers sufficient time to think about the matter and prepare a response. As a result of that, changes had been made in the protocol for the HCC sharing information with the DH, and it had made Mr Bradshaw more aware of the possibility of there being other poorly performing trusts.[198] However, he was quite clear that Ministers should not interfere in the conduct of an investigation by an independent regulator and should only comment once it had reached its final conclusions:

> *... what was absolutely paramount to me was that the independent regulator, who had unearthed this problem, and were doing the work investigating it, should be allowed to get on with their inquiry. They had the powers that they needed, if necessary, to ensure that the hospital was put in special measures, new management put in, services were closed down if necessary. They didn't do that, although I gather from Anna Walker and Ian Kennedy's evidence that they thought about it very carefully. And until they had completed their inquiry and reported, that was when the Government or the Department had to respond.*[199]

19.173 The same position was adopted by Sir Bruce Keogh that there was no case for intervention by the DH:

> *... in the light of also getting assurances from the Healthcare Commission ... that at numerous points in this chain where I and others asked the Healthcare Commission, "Is any intervention required?", the answer was always "No", because there was an expectation that things were improving. So, the Department of Health itself is not the regulator, and neither should it be, but the Department of Health should listen to the independent regulator, otherwise there's no point having an independent regulator, and that regulator was telling us that there was no need for operational intervention. Now, I'm not a performance manager but I do recognise your point that things were bad, and I also recognise that we were being told at that time that the Healthcare Commission and others were all over this. So I think there is something for your deliberations and it would be, I think, a useful part of your deliberations to think at what point who gets involved in different levels of performance management as part of the regulatory system.*[200]

197 Bradshaw T116.127
198 Bradshaw WS0000060265–266, para 66–67
199 Bradshaw T116.125–126
200 Keogh T123.49

Department of Health reaction to the Healthcare Commission report

19.174 It is fair to say that the final report of the HCC investigation was a considerable shock to all at the DH.

19.175 The same cannot be said for drafts of the report that reached it earlier. An "extract of the draft" of the report, which included the main sections but not the recommendations or an executive summary, was sent to the DH on 18 December 2008 for comment.[201] Whilst it was said that conclusions were excluded, the draft included many findings of fact, together with detailed descriptions of the evidence relied on. For example:

- An analysis of standardised HRG chapter-level mortality was said to show that: "Rather than being able to pinpoint one clinical area causing higher than expected mortality, these findings are indicative of systemic problems across the trust's emergency care system";[202]
- The same observation was made in relation to 30-day mortality;[203]
- The Trust had made a "very limited" response to the HCC's concerns about mortality;[204]
- A case note review of 10 stroke cases by experts had concluded that in five there was no indication that opportunities to discuss, learn and improve had been taken. This included an apparent deficiency in the arrangements to prevent deep vein thromboses, and poorly executed fluid records;[205]
- In a review of eight cases that had been considered by the Trust's mortality group as raising no issues for concern, issues were found in all eight. These included concerns about the correctness of fluid administration, complaints by relatives about nursing care, lack of review by a senior doctor and lack of intervention following a high Modified Early Warning Score (MEWS);[206]
- The report summarised some of the complaints received by the HCC from over 100 patients and relatives. These included some of the stories all too familiar to this Inquiry about cleanliness in the wards and hygiene, with specific mention, for example, of faeces often being left splashed on the bedside, armchair and lockers;[207]
- Analysis of complaints suggested long-standing concerns about the quality of nursing care;[208]
- There were too few staff to perform triage in A&E, which was being carried out by administrative staff, and there were examples of patients who had been adversely affected;[209]

201 Keogh WS0000065271, para 46; BK/18 WS0000065559
202 BK/18 WS0000065581
203 BK/18 WS0000065581
204 BK/18 WS0000065586
205 BK/18 WS0000065588–589
206 BK/18 WS0000065590
207 BK/18 WS0000065596; WS000000655660–661
208 BK/18 WS0000065598
209 BK/18 WS0000065605

- The now well-known staffing issues were described;[210]
- Staff considered that priority was given to the four-hour A&E waiting time target over patient safety;[211]
- The Royal College of Surgeons (RCS) review for surgery in 2007 was referred to and its finding that there were too few protocols;[212]
- A description of the unsatisfactory state of clinical audit in the surgical division was given;[213]
- Numerous and detailed criticisms of the overall governance of the Trust were made.[214]

19.176 The report also described progress made by the Trust since the start of the investigation. The points noted included:[215]

- It was acknowledged that the Trust had responded positively and rapidly to the concerns that had been raised by the HCC about A&E in May 2008;
- Nursing staff had been recruited for A&E, but this had largely consisted of replacing experienced nurses who had left with inexperienced ones;
- Triage was now being conducted by qualified nurses;
- Requested equipment for A&E was still on order;
- A rapid training assessment in the use of MEWS had taken place;
- No breach of the hygiene code had been found in recent inspections.

19.177 David Flory told the Inquiry that he did not read the draft at this stage as he was aware that the complete report would follow shortly.[216]

19.178 Following receipt of the draft, a meeting took place on 15 January 2009 between Sir Bruce Keogh, Mary Newman (who led the DH sponsor team for the HCC), Sir Ian Kennedy and Anna Walker. Sir Bruce told the Inquiry that there was no suggestion at the meeting that the situation had changed substantially from that outlined in the HCC's statement on 18 March 2008 or that urgent operational intervention was required:[217]

> *We were very aware that the situation at the Trust had been very serious in the past but in the absence of a recommendation for special measures or advice to similar effect from the HCC, we were not aware that immediate intervention might be required. We had not yet received the final version of the report which was as yet incomplete, so all we could do was await the outcome of the HCC's deliberations.*

210 BK/18 WS0000065610–613
211 BK/18 WS0000065616
212 BK/18 WS0000065643–644
213 BK/18 WS0000065654–656
214 BK/18 WS0000065662–693
215 BK/18 WS0000065694–699
216 Flory WS0000066629, para 51; Flory T121.130–131
217 Keogh WS0000065271–2, para 51. The minutes of the meeting [BK/20 WS0000065719] merely recorded the expected publication date

19.179 Sir Bruce accepted that he now had a more detailed knowledge having seen the draft report, but there had been a number of discussions going on with the senior team at the HCC about the requirement and necessity for intervention, and at no point did the HCC ask for that to be done.[218] He was asked whether, if this case was to be seen as being as serious as Maidstone and Tunbridge Wells, an independent judgement had not been required:

> *THE CHAIRMAN ... I just wonder whether if it was being thought of in those terms, which one can quite understand, there didn't need to be some form of at least independent judgement being made in the Department or consideration to whether circumstances were safe on the ground?*
>
> *A. I think that's a fair comment, but we didn't do it.*[219]

19.180 On 4 February 2009, Rt Hon Alan Johnson MP, Secretary of State for Health, met Sir Ian Kennedy for a routine "catch-up". Mr Johnson was caused considerable concern by being warned by Sir Ian about the import of the impending report on the Trust and having received no prior warning of this in his briefing for the meeting. Mr Johnson was moved to write:

> *Hugh needs to know that there will be a very difficult report from the Healthcare Commission on Mid Staffs which not only says emergency patients died unnecessarily but implicates Cynthia Bower, the CQC secretary* [sic]. *It wasn't even mentioned in my briefing for the meeting with Ian Kennedy and my office has no knowledge of it, but somewhere in the Department this draft report is ticking away like a time bomb. Shades of Maidstone and Tunbridge Wells.*[220]

19.181 Sir David Nicholson agreed that Ministers should not be put in the position described.[221] David Flory told the Inquiry that this episode was the first time he had become aware of the full extent of the HCC's concerns. He then read the findings of fact referred to above. Having done so:

> *I ... was left in no doubt about the appalling standards of care that the Commission had identified. I was shocked and surprised that the investigation had raised issues of such scandalously poor treatment of patients.*[222]

19.182 A briefing note was prepared for Ministers on 11 February 2009.[223] It stated that it was not currently likely that the HCC would be recommending special measures.[224] The note included

218 Keogh T123.55–56
219 Keogh T123.57
220 BK/21 WS0000065725
221 Nicholson T127.196
222 Flory WS0000068630, para 54
223 Flory WS0000066631, para 56; DF/21 WS0000066975
224 DF/21 WS0000066979

a copy of a letter from Nigel Ellis, Head of Investigations at the HCC which confirmed that it had been content that the Trust had acted appropriately in response to the concerns.[225] Mr Ellis confirmed this view in his evidence to the Inquiry that the HCC had not required the Secretary of State to take any further action, although the situation had been "very serious".[226] A summary of all the critical findings of fact was annexed to the note. On receiving it, Mr Johnson's Private Secretary responded. Describing the summary of the findings as "quite damning", she asked for the submission to be amended to make clear, among other things, whether the Trust and the DH agreed with the findings, and what, if any, action had been taken to improve governance and performance. She commented that the Secretary of State:

> *... will be more reassured by a "warts and all" note from officials, that lets him know how we intend to respond. He was quite alarmed by the picture that Ian Kennedy painted ... and I think the note needs to do more to reassure him that we've got a grip on this report.*[227]

19.183 The 11 February 2009 was also the first occasion on which Sir David Nicholson saw the draft report.[228]

19.184 On 11 March the Secretary of State, David Flory, Dr Bill Moyes, Anna Walker and Nigel Ellis took part in a meeting to discuss the final report. The discussion about the handling of mortality figures has been discussed in other chapters.

Recent changes to the system

19.185 Since the period principally under review by this Inquiry, the DH has introduced a number of changes which need to be taken into account when considering the applications of the lessons to be learnt from the Mid Staffordshire experience.

National Quality Board

19.186 The NQB provides a forum for the leaders of all the major organisations in the healthcare system. It provides a means to clarify roles and responsibilities and to coordinate policies and action. It has produced a series of reports and recommendations including:

- In February 2010, the publication of *A Review of Early Warning Systems in the NHS*.[229] The purpose of this was to look at how early warning signs could have been picked up,

225 DF/21 WS0000066980
226 Ellis T80.159
227 DF/22 WS0000066996
228 Nicholson WS0000067702–703, para 234
229 UOB/28 WS0000059967

and the appropriate organisations alerted and involved so that action could be taken quickly.[230] Its recommendations included:[231]

- Trust Boards be given further guidance on how best to govern for quality;
- The DH should work with Royal Colleges, including the Academy of Medical Royal Colleges, and the specialist associations, to look at how professional bodies can encourage a culture of openness and transparency among all healthcare professionals;
- The role of commissioners to safeguard quality was vitally important, and it therefore welcomed the extension of the NHS performance framework to PCT commissioners;
- Separate compliance frameworks such as Monitor for FTs and the NHS Performance Framework for NHS trusts continue to be moved into close alignment and are revised to make them more sensitive to quality issues so as to allow underperformance in quality to be spotted;
- The NQB conduct a review of patient engagement and feedback mechanisms in order to better understand where they are working well and where more could be done and how well this is connecting with Trust Boards and the decision-making process;
- A single organisation should be responsible for making sure that all action taken, whether regulatory or management, is aligned and coordinated. The report recommended that SHAs take up this role.

- The NQB revisited this report as part of a two-phase review about maintaining and improving quality during transition. The phase one report titled *Maintaining and Improving Quality During the Transition: Safety, effectiveness, experience* was published in March 2011 and focused solely on the transition year of 2011/12. It emphasised that quality should remain the guiding principle as organisations moved to implement NHS modernisation. It also described key roles and responsibilities for maintaining and improving quality and emphasised the importance of an effective handover of knowledge and intelligence on quality between old and new organisations;[232]
- In March 2011, *Quality Governance in the NHS – A guide for provider boards* was also published alongside the above transition guidance. This provided advice for Trust Boards on governing for quality.[233]

Mortality statistics

19.187 Following on from the recommendations of the first inquiry, significant progress has been made in seeking greater consensus around the statistical methodology for analysis of mortality rates. A new methodology (Summary Hospital-level Mortality Indicators (SHMIs)) has now been agreed by a working group and is to be published alongside HSMRs by the Health and Social Care Information Centre. Various recommendations are made in *Chapter 5: Mortality statistics*.

230 O'Brien WS0000059334, para 80
231 UOB/28 WS0000059967, pp49–53
232 Keogh WS0000065312, para 183; *Maintaining and Improving Quality During the Transition: safety, effectiveness, experience – part one 2011–12* (March 2011), National Quality Board; www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_125497.pdf
233 Keogh WS0000065312, para 183; BK/45 WS0000066295

Quality Accounts

19.188 Lord Darzi's *High Quality Care for All* stated that any healthcare organisation that provides an NHS service would be required to publish Quality Accounts from April 2010. The requirement to publish a Quality Account is set out in the Health Act 2009[234] with the exemptions and requirements on the content of Quality Accounts set out in the NHS (Quality Accounts) Regulations 2010,[235] which were amended in 2011.[236] The reasoning behind Quality Accounts is that they would force Trust Boards to give an equal focus to quality and quality reporting as to money and financial reporting.[237]

19.189 The Quality Accounts seen suggest that these are a potentially very valuable means of enabling the public and regulators to have basic information about a provider's performance in relation to standards and other measures of quality. Having set up this system, it is necessary to develop it to enable it to fulfil its purpose more effectively. In particular:

- Quality Accounts should be required to be produced with a consistent presentation and to contain information with regard to compliance with fundamental safety and enhanced quality standards in an accessible and comparable form. Whilst organisations must be left with the freedom to include information about their values, aims and successes, it is the hard facts about performance that should be presented transparently so that areas required for improvement are as prominent as areas in which compliance has been achieved. A prescribed list of data required to be presented in reports and the form in which it should be presented should be produced and reviewed regularly;
- Quality Accounts, like financial accounts, should be verified by independent external audit. Such an audit should examine the supporting evidence relied on for reported results and establish whether it justifies statements made;
- Quality Accounts should be required to contain the observations of commissioners, overview and scrutiny committees, and Local Healthwatch.

Incentives for quality

19.190 In April 2009, the Commissioning for Quality and Innovation (CQUIN) payment framework was introduced. This is a national framework for locally agreed quality improvement schemes and allows commissioners to reward excellence in provider services by paying a quality increment to providers using NHS standard contracts if they achieve agreed quality improvement goals.

19.191 The scheme operates to reflect both local and NHS operating framework priorities and serves financially to incentivise providers.

234 www.legislation.gov.uk/ukpga/2009/21/part/1/chapter/2
235 www.legislation.gov.uk/uksi/2010/279/contents/made
236 www.legislation.gov.uk/uksi/2011/269/made
237 Keogh WS0000065303–305, para 152–156

19.192 In the 2010/11 scheme, acute providers also had to include certain mandatory defined goals, each with a specified indicator. These were:

- Reduce avoidable death, disability and chronic ill health from Venous Thromboembolism (VTE);
- Improve responsiveness to personal needs of patients.

19.193 These two goals were also included in the 2011/12 acute CQUIN schemes.

19.194 As a result, Sir Bruce Keogh confirmed that from June 2010 trusts became eligible to receive an incentive CQUIN payment from their local PCT if they were able to demonstrate through a new national data census collection that they routinely assess patients on admission for risk that they will develop hospital-associated VTE. He stated that the DH was seeing a steady improvement in trusts able to demonstrate this.[238]

19.195 The DH guidance to the scheme published in December 2010 set out the rate of uplift, which a provider would receive for successfully meeting agreed quality agreement goals. In 2010/11, this was 1.5% of the value of the provider contract and had increased from 0.5% in 2009/10.[239]

19.196 Dr Judith Smith, Head of Policy at Nuffield Trust, in expert evidence to the Inquiry, described the positive effect of such a scheme in that:

> *It in a sense gives potentially commissioners much more leverage to start connecting the amount of money they give to providers with the outcomes or the quality measures. It certainly has put in place a framework that could be used for that much more extensively in the future.*[240]

19.197 Dr Rashmi Shukla, the WMSHA Medical Director and Regional Director of Public Health, highlighted the recent use of such a tool in focusing on quality of care, stating:

> *Really, it's only now that we have specific measures that are focused on quality of care, specific focus on having clinical quality review meetings, and what's called CQUINs, which are commissioning quality improvement through the contract, which is now, you know, again as I mentioned, legally binding for foundation trusts.*[241]

238 Keogh WS0000065307, paras 162–166
239 *Using the Commissioning for Quality and Innovation (CQUIN) payment framework – A summary guide* (December 2010), Department of Health, p8
240 J Smith T6.87
241 Shukla T69.37

19.198 Eamon Kelly, former WMSHA Director of Commissioning and Quality, told the Inquiry that:

> *We now do link 1.5 per cent of the total contract value to performance against quality measures ... I think there is some evidence that that is having an effect on improving quality ...*[242]

19.199 Although he welcomed the CQUIN system, he did express a degree of caution as to how this could work in practice given the need he saw to work collaboratively with providers:

> *Increasingly, there have been clauses that provide for financial penalties to be made. And in the case of CQUINs payments for incentives, and that is a journey we've been on, and I think the policy intention is that over time a greater proportion of contracting will be tied to quality performance. And I think that's right. But I also think it's right to ensure that that's done within the context of both parties working together openly and maturely to improve care where both parties have a contribution to make.*[243]

19.200 The Inquiry's *Report from the Forward Look Seminars* summarised the attitude of participants to CQUIN as follows:

> [Clinical Commissioning Groups] *need to be prepared to use contract levers and incentives imaginatively to encourage a focus on the outcomes they want to secure for their patients, including a specification of the information to be collected and shared. While the national contract allows for some incentive payments for quality (CQUINs), some argued that local commissioners might want to negotiate a higher percentage.*[244]

19.201 It is important that commissioners receive the tools, resources and training to enable them effectively to use incentivisation for quality in their commissioning arrangements.

National Institute for Health and Clinical Excellence quality standards

19.202 The use of NICE for the development of quality standards is addressed elsewhere in this report, but must be regarded as a positive development, more likely to engage clinicians in their formulation and in compliance than previously has been the case.

242 Kelly T75.64
243 Kelly T75.66
244 *Report from the Forward Look Seminars* (November 2011), Dr Sarah Harvey, p56; www.midstaffspublicinquiry.com/inquiry-seminars

Indicators of Quality Improvement

19.203 In the summer of 2008, Sir Bruce Keogh set up the measuring quality programme in order to encourage organisations to measure their clinical quality. As part of this, the Health and Social Care Information Centre was asked to establish and maintain a database of quality indicators.

19.204 In April 2009, the Indicators of Quality Improvement (IQI) database was launched following widespread consultation with the NHS, the Royal Colleges and other professional staff groups. It was implemented so that further suggestions as to indicators could be made to the Information Centre to enable input from clinical and wider NHS staff.[245]

19.205 Further development of IQI was conducted by the National Quality Indicator Development Group which tasked the Information Centre to ensure development of quality indicators using sound statistical methodology and involved clinical experts, information analysts and wider NHS staff.

19.206 Initially, 450 indicators were drawn up, which following consultation with trusts nationally, were narrowed to 150 measures that were agreed to be useful. These formed the basis of the IQIs which had been developed to enable trusts to download their raw data from the website in order to assess their performance against other organisations. The latest version of the IQI menu now includes almost 300 indicators for quality improvement across a range of specialities.[246] Sir Bruce emphasised to the Inquiry:

> *This is not a monitoring tool. This is meant to be helpful information to enable people to look at how they're performing themselves and do whatever analyses they want. We haven't done that enough in the service, I don't believe.*[247]

19.207 Sir Bruce went on to explain how further development of the IQIs had been done through the work of the Quality Information Committee. This built on the work of the quality information strategy subgroup whose report was published in June 2010 and recommended improving information publicly available, data quality, communicating information and rationalising the organisational structures collecting data.[248] At the time of his evidence he stated that the Committee was looking at ways to improve data quality and how in future the development of new data collection might be prioritised. The Committee was also said to provide independent national advice on quality indicator development including on the development of new indicators for the NHS outcomes framework.[249]

245 Keogh WS0000065290, paras 115–116
246 Keogh WS0000065290, para 119; BK/32 WS0006000223
247 Keogh T123.117
248 Keogh WS0000065292, para 124
249 Keogh WS0000065292, para 125; NHS outcomes framework documents, www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_131723.pdf

Supporting NHS leadership capacity

19.208 It has been noted in the evidence before the Inquiry that the tenure by an individual of a trust chief executive's post is short. The average is said to be two to three years.[250] Yet it is the minority who have remained in post for a significant length of time who are regarded as running the successful trusts. Sir Andrew Cash, as a Chief Executive himself, told the Inquiry:

> *... the wastage rate is high ... there is a group of a hundred or so chief executives who have been in their post for ten years or more, and they're normally in successful organisations, actually. And I think that is because the governance is very clear and particularly on the clinical outcome of the patient experience and on the staff engagement. And it is very important that the chief executive gives primacy to their medical director, chief nurse, on any issues to do with safety, so they can stop anything that's going on anywhere and say, "I am concerned clinically about what is going on here", and then the whole organisation stops to actually double-check that. And I think when you're in a ... place for some time you get into recruiting and developing very, very good people throughout the organisation that are able, in the right culture, to ... say these sorts of things. So I do think that we have to think very carefully about the skills of people who become chief executives and their talents and so on. And we are in a position where people can assume a post ... and almost have no training at all in ... doing it, and it is a pretty daunting task to take on. So I think people need to be trained and have a skill set and helped through. And particularly so in terms of the new architecture that is emerging out of the National Health Service coming up, clinical commissioning groups and NHS foundation trusts and so on.*[251]

19.209 Various attempts have been made by the DH to address the issue of training and support for executive leaders.

19.210 One such initiative was the establishment of the National Leadership Council (NLC) which was established to support and strengthen leadership within the NHS. In establishing this body, the aim has been to provide benefits to patients, the public and staff by encouraging and supporting change and progress within the NHS. This did not progress past 2010.[252] The failure of this and other initiatives appears to be a result of the lack of certainty and standardisation of what the leadership roles within the NHS are and the levels of support offered to individuals within trusts.

19.211 The launch of the NHS Leadership Academy was announced by the Secretary of State in June 2011 with the aim of developing, sustaining and promoting leadership throughout the NHS. The Leadership Academy's intention is to bring together the work of both the NHS Institute

250 Nicholson T127.133
251 Cash T119.120–121
252 http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Aboutus/HowDHworks/BoardsandCommittees/NationalLeadershipCouncil/index.htm

Leadership Team and NLC in order to focus and centralise national leadership activities. The intention is for it to link with regional trusts and set a benchmark for best practice for health service leaders.[253] Whether the establishment of the Leadership Academy will effectively deal with the issue of autonomy within trusts and the absence of centralised leadership training and support remains to be seen.

19.212 In addition, the Academy of Medical Royal Colleges is currently setting up a Faculty of Medical Leadership and Management.[254]

19.213 The impression is that training for leadership roles still lacks a sense of coherence and is subject to initiatives which are initially promising but are then allowed to fade away.

19.214 The issue is further considered in *Chapter 24: Leadership in healthcare*.

Department of Health culture

The Chief Medical Officer's perspective

19.215 Sir Liam Donaldson, as the Government's former Chief Medical Officer, sitting for some years within the DH, was able to offer a unique personal perspective on how the DH caused change to occur and why it had not succeeded until recently in placing quality at the top of its healthcare agenda. He said that although the NHS was not quite like the army, it was hierarchical and that if those at the top kept on saying something, in the end those further down did it:

> *I think a classic example would be the attention that was given to healthcare infection. It's a very important topic but it is quite a circumscribed topic, but the Secretary of State of the day, John Reid, became very seized of the importance of doing something about this and he spoke about it all the time, so did the chief executive, Nigel Crisp, and so did the other* [officials] *– and as a result of that the NHS didn't just listen, but they felt that they really needed to pay very, very serious attention to this. Now, that wasn't the case with quality more generally ... I don't want to sort of blow my own trumpet at all, because I wasn't running the NHS, but ... I gave a huge number of conference speeches and was always talking about quality, but not everybody was, and that's not a criticism, it's just that I'm not sure that in their heart of hearts everybody was convinced that you could run a service which met the financial and productivity targets but also delivered quality. And I said ... in one meeting I can remember, "Why can't the business plan and the quality plan be one and the same document? Why do we have to have two separate documents?" And that, I think, is – is at the heart of it.*[255]

253 Leadership Academy Website: www.leadershipacademy.nhs.uk/
254 *Establishment of a Faculty of Medical Leadership and Management,* http://aomrc.org.uk/about-us/news/item/establishment-of-a-faculty-of-medical-leadership-and-management.html
255 Donaldson T122.20–21

19.216 Clearly there were occasions when he felt frustrations, such as when at his first meeting with an incoming Secretary of State he threw on the desk photographs of children killed through medical error:

> *And so it was – advocacy – constant advocacy and persuasion, until eventually, around the time of Lord Darzi's report and subsequently, the top people are now saying quality, quality, safety, safety, and then the NHS listens. But … leadership from the top is very, very importance* [sic].[256]

19.217 He agreed that it could be too easy for those at the top of this vast system not to keep at the forefront of their minds the effect of their decisions on patients:

> *THE CHAIRMAN: … do you think it's perhaps too easy at the higher echelons, and I don't mean just mean secretaries of state but in the Civil Service and the NHS, for people to forget the effect of what is happening on real people?*
>
> *A. I absolutely agree with that, and … that's why I … tried to bring patient – the experience of patient stories about patients into the … equation … and I often said to people, "Think about your family, your friends, neighbours. Ask them about their experience of care". And most people's experience of care is fairly positive, … but equally most will comment on some aspect of care that is negative, not necessarily of the whole episode of care. And I would say to my staff, "Well what … are our policies doing to help this? Have we got the right policies? Are they being implemented properly?" So I absolutely agree that – ironically – although people are very cynical about politicians, ironically I think that the politicians are often the ones who do have the sharpest appreciation because they have their constituents and they have other MPs coming up to them in the lobby telling them about a constituent. So I think they often have a sharp appreciation of some of the realities.*[257]

19.218 The ability of the DH to require things to be done had, he thought, been put to good use in the development of access targets. He considered targets of this nature could be and had been, beneficial, but it was necessary for them to encompass the whole of a treatment rather than to capture aspects of it which could be provided but still leave the patient without the desired and obtainable outcome.[258]

19.219 In 2006, Sir Liam commissioned *Safety First* to assess what progress there had been in promoting a patient culture. It concluded that although the profile of patient safety had been

256 Donaldson T122.22
257 Donaldson T122.23–24
258 Donaldson T122.26–27

raised at national level, NHS managers were still focusing on access and financial targets. Asked why this was the case, Sir Liam offered as an explanation:

> *... there hadn't been a particular tradition of quality and safety being explicitly recognised and pursued and measured in the NHS over many, many, many years. And, secondly, because I think the idea in NHS management, the principal idea is about running an organisation that is sound financially and is productive, as far as the numbers and nature of patients that it treats, with quality matters being left to the clinicians. I think bringing quality and safety to a more general level at the board level, a general management level, hadn't happened, but as I've explained there were a number of us fighting very hard to make sure that it was.*[259]

19.220 The same point had been put by Sir Liam at the first meeting of his working group set up as part of Lord Darzi's review, as recorded pithily in the minutes quoted earlier in this chapter.

19.221 Sir Liam pointed out that in publishing a report such as *Safety First*, which was critical of the current position, he was being bold and to an extent breaking with tradition:

> *I should point out, and I hope you won't mind me saying this, that you're quoting a lot of my documents in which I'm saying very critical things about the NHS. It is rather unheard of for someone in my position to do that. So that was part of I was trying to push the boundaries as far as I could to try and challenge the system constantly, because traditionally a civil servant, which is what I was, was not allowed to criticise the Government or the system at all. So I say that because if you are suggesting that it I was too timid in my approach to some of these things, I think I was being quite bold for the day.*[260]

19.222 He was in favour of a more robust attitude being taken with regard to patient safety and quality comparable to that adopted on financial matters:

> *... it may well be that if some of the tougher talk about whether a manager was delivering or not was based around the quality of the service, then I think the message that their livelihood depended as much on that as on money, then I think the message could have got through better.*[261]

259 Donaldson T122.98–99
260 Donaldson T122.100–101
261 Donaldson T122.102

Consultancy reports

19.223 A series of consultants' reports were commissioned as part of Lord Darzi's review. They were not published at the time as they were regarded as advice to Ministers. They gathered together a number of critical comments about the DH from various stakeholders from which conclusions were drawn about the presence of a "top-down" culture of fear and a failure to use information effectively, among other concerns. A summary is provided earlier in this chapter.

19.224 Various DH witnesses were asked for their reactions to these criticisms. Sir Liam Donaldson, who commissioned these reports, thought the JCI report was very negative and needed to be seen in the context of other input into the Darzi process showing how much good work was being done:

> *I think that some of it is unfair, and not supported by the proper evidence and rational argument, but nevertheless we took it along with other submissions and it went into the melting pot that led to all the proposals in the Darzi review.*[262]

19.225 He characterised some of its content as "exaggerated", "not well founded" and amounted to quotations from 50 anonymous people against the thousands of others who had participated in the review. He roundly condemned the quality of the report as he rejected its suggestion there was a "culture of blame":

> *I don't recognise that, quite honestly. I think that there have been tough decisions made about the performance of some managers in the NHS, but they'd been the minority, and some of them have been in situations like the Stoke Mandeville situation and the other hospital, where there were deplorable standards of hygiene and patients died as a result. So I think, in those circumstances, people do have to be held to account. So I don't know ... what evidence they've got that it operated any more widely than that. So that's the sort of reaction that I think those of us who looked at this report had. It was a very short visit, by two individuals and we were, frankly, very, very disappointed in the quality of the report. I know the joint commission very well. They are the main regulator, a voluntary regulator in the US, and I have never seen one of those reports as poor quality as this on whatever subject.*[263]

19.226 However, he would have agreed with it if it had concluded that a culture of blame is detrimental to good patient care and that there were systems in the world that dealt with it better than the NHS.[264]

262 Donaldson T122.103–104
263 Donaldson T122.107
264 Donaldson T122.108

19.227 He was prepared to place more store by the IHI report. With regard to its finding that the NHS had developed a widespread culture of fear and compliance, which on the face of it was consistent with the JCI finding of "A shame and blame culture of fear" in the NHS, he said:

> *It is there quoting the outcome of interviews, which is fair enough if that's what people told them. They interviewed the same people, as far as I remember, so they told them the same thing. But it's how they then drew some overall conclusions, and it's, I think, a much more balanced report. It does have those negative strands in it from the interviews, but it also draws an overall – some very positive conclusions about ... where the NHS is on its journey on quality and safety.*[265]

19.228 He placed more weight on this report because it came to the positive conclusion that the NHS had the potential to become a system that led the world in equity and all aspects of quality.[266] He accepted that the authors of the report had sought views from senior NHS figures of substance, but then argued that such observations should be approached with caution:

> *THE CHAIRMAN: But we're not talking about people given to superficial comments in the pub. These are people of substance, aren't they, and of seniority?*
>
> *A. They are indeed, but I found in my career that when given the opportunity to criticise the Government or the layer above, them in the system, people usually take that opportunity, particularly if there's no penalty associated with doing that. So I think people say things in that situation, which maybe in a measured discussion they probably wouldn't say.*[267]

19.229 Sir Bruce Keogh, who only saw the report for the first time shortly before giving evidence, said he did not recognise, certainly in the DH, the suggestion in the JCI report that there was a culture of fear, although he thought that there were other good points in it, if that one were "downplayed".[268]

19.230 David Flory, who had not seen the JCI report until shown it for the purpose of the Inquiry, said that he did not recognise the existence of a culture of bullying in the DH.[269] He considered that statements made in the report in support of this assertion were "outrageous", in particular a quoted suggestion that the HCC saw humiliation as a driver for improvement.[270]

265 Donaldson T122.112
266 Donaldson T122.112–113
267 Donaldson T122.113–114
268 Keogh T123.129
269 Flory WS0000066621, para 22; Flory T121.17–19
270 Flory T121.21

19.231 David Flory also rejected the notion that performance management by use of targets should foster poor practice by reason of fear of the consequences. He described his approach to performance management from his perspective, having been the DH Director of Finance, Performance and Operations and then NHS Deputy Chief Executive, in relation to trusts that failed to meet their waiting time targets:

> *When I get ... my latest monthly update numbers, of course I go down that list of who they are and I look at where their performance was last month and the month before, and I look at the plan that's been put in place to improve ... Is this where we expect them to be by now? I don't go down the list and phone up those organisations and say, "Clear your desk and go home, you've missed your A&E target this month" ... we talk about fear of the consequences of these things. My response to the consequences of this target is: are we learning from what's gone wrong and is it being put right? Now ... if it is, then we move on to the next month. If there are new problems emerging that we need to understand, then we need to start to understand them and learn where we go on. If we get to a stage where someone says – or where an organisation isn't hitting the target, and they say, "We don't think it matters", or, "We're not trying", that is unacceptable. You cannot draw a taxpayer-funded salary and ignore the rules of the game that the taxpayer, through the elected Government of the day, is setting.*[271]

19.232 David Flory did, however, accept that by the time concerns had filtered down the management chain to the front line, the pressure could be felt to be intolerable, but only where local management was not being managed adequately.[272] He also accepted that there remained a problem in persuading some managers to look out to their communities rather than up at the DH.[273]

19.233 Sir David Nicholson rejected the JCI report as not being "significant".[274] He did not agree with the overall conclusions of that report about the healthcare system. He rejected the notion that there was a culture of fear in the system:

> *Q ... Do you accept that there has been a culture of fear within the NHS, and people looking up and not out, as I think you put it?*
>
> *A. I don't believe that there is a culture of fear in the way that you describe it, and I don't believe that because ... I've worked – I've been in the Department for the last six years. I've worked in the NHS extensively. I don't – I've never recognised that way of describing it.*[275]

271 Flory T121.58–59
272 Flory T121.59–60
273 Flory T121.65–66
274 Nicholson WS0000067721, para 293
275 Nicholson T128.95–96

19.234 He admitted that he was aware that on occasion undesirable "short cuts" had been taken by managers:

> *Sometimes, though, the conversation is, "We're going to miss the four-hour target, put her in that room". And that's a bad place for us all to be in. And I've seen that happen and people will describe that a short cut is made to something which is more important than just the short cut. So I've seen circumstances where people under pressure have said "just do it", and that is a bad place for the NHS to be in. And it's something we've been trying to move away from significantly.*[276]

19.235 He distinguished that sort of behaviour from the need for clarity of expectations when organisations were not working as they should:

> *With organisations that consistently fail to enact all of that, I think it's perfectly reasonable for a central body, an organisation, to make it very clear what your expectations are. Now, that's not to say you run by a climate of fear. But you need to be very clear, I think, when you know that particular actions will improve services for patients that you are unequivocal about what your expectations are as that goes forward. But they're relatively rare. There aren't many things like that and in fact the danger with most of them is the unintended consequences can be worse.*[277]

19.236 Sir Hugh Taylor described the report's suggestion that there was failure to use information appropriately as a "caricature", which like all caricatures, had an element of truth in it.[278] He pointed out that the DH had invested a great deal of time and effort in supporting trusts to make improvements:

> *Nevertheless, underlying this line of argument was, I think – a point was being made about the importance of re-engaging clinicians with the quality agenda, and a very good illustration of that is given in the paragraph that you quoted to me, because I think one of the frustrations for many of us in the system was that trusts themselves, even professionals within those trusts, were not making sufficient use of data, there wasn't enough attention being given to benchmarking across organisations, and it became one of the insights really of the High Quality Care for All programme, and then report that it was precisely that agenda which we needed to address next.*[279]

276 Nicholson T128.96–97
277 Nicholson T128.97–98
278 Taylor T126.91–92
279 Taylor T126.94–95

19.237 Una O'Brien thought that the JCI report overstated its case, although she did partially accept some of its conclusions:

> *I think it overstates the case, but there is a strong strand of truth in what it says.*
>
> *So I think these encapsulating phrases about, you know, a single style of management, everybody feels the same say and all data is this rather than that, I think that that is massively oversimplifying the reality of what actually went on, and the truth is that you find a complete distribution of practice at this time throughout providers, I would argue.*
>
> *So I think to the extent that you pull people in and ask them to tell you some hard truths, they certainly did, but I wouldn't accept it as a lock, stock and barrel characterisation of absolutely everything at the time, because I do not think that that is remotely fair to the very large number of doctors and nurses up and down the country who I know at this time would have been working on these things.*[280]

19.238 The Rt Hon Andy Burnham MP told the Inquiry that the drive of the changes made over the years had been to diminish the "top-down", "command and control" approach which had given rise to suggestions of a culture of fear and blame in the past:

> *... the drive had been towards if that culture was embedded in certain places, challenging it and getting rid of it. That was very much the drive of the FT reform and many other reforms that we put in place when we were in Government. So I recognise that there was a top-down command and control style in the NHS that had led to these kind of accusations in the past, but essentially the drift of the reforms that we've been discussing today were intended to break that.*[281]

19.239 It is fair to note the local evidence of Mr Yeates, Mr Newsham, Ms Bower and Mr Brereton who all denied that there was any unreasonable pressure felt by them.[282]

Reorganisation

19.240 One feature of the DH's policy frequently commented on by witnesses has been that the reaction to dissatisfactions of one sort or another has been to restructure elements of the system. Some of the perceived consequences of this approach have been seen in other chapters.

19.241 Sir David Nicholson commented that this was less likely to be the approach in the future as the Secretary of State's powers would be more limited:

280 O'Brien T125.132
281 Burnham T115.198
282 Yeates WS0000074950, para 96; Newsham T60.133, WS0000011958, para 154; Brereton WS0000037206, para 50; Bower WS0000021004, para 99

... one of the things I think about reorganisations of the past is there's always been this view that if we sort of slightly got it wrong, the Secretary of State would have the power to put it right. This set of changes are not like that. They do set the powers of the Secretary of State in a particular legal framework, and so in future secretaries of state will find it much more difficult to reorganise the NHS, much more difficult because they'll have to go through a legislative framework in order to do it. Up till then, of course, secretaries of state having literally been able to publish documents and make changes happen. So although it is a big change, and although it's highly controversial and going through Parliament at the moment, I think if we get to that place I think it will make it much better for us in terms of getting the consistency and continuity that we need to take the NHS forward.[283]

19.242 He told the Inquiry that there had been more consideration about the possible risks of the changes being proposed by the Secretary of State on the occasion of the current reforms than had been the case in the past and that the DH had, for example, also considered options that would not require primary legislation.[284]

Response to previous reports

The NHS Constitution

19.243 One measure by which the DH has sought to spread a consistent and positive culture through the system has been by the NHS Constitution. In its closing submissions, the DH fully recognised the importance of culture in a system as large and complex as the NHS and suggested that by the development of the Constitution it had clarified the purpose and principles of the NHS and the values and behaviours expected of NHS staff.[285]

19.244 Under the Health Act 2009, all providers and commissioners are required to have regard to the NHS Constitution in all their decisions and actions.[286] The words "have regard" infers an obligation to consider the Constitution, but no more. Neither the Health Act nor the NHS Constitution states that there are any sanctions where an NHS body fails in this duty. Therefore, the NHS Constitution appears to be a set of guiding principles to be considered, rather than a set of propositions to which organisations will be legally bound.

19.245 The NHS Constitution brings together in one place details of what staff, patients and the public can expect from the NHS and sets out the rights of an NHS patient. These rights cover how patients access health services, the quality of care they will receive, the treatments and programmes available, confidentiality, information and the right to complain if things go wrong.

283 Nicholson T128.93
284 Nicholson T128.95
285 CLO000000864/867, DH Closing Submissions, paras 162 and 169
286 Health Act 2009, section 2

19.246 Seven key principles are stated and required to be a guide to the NHS in all it does:

- To provide a comprehensive service available to all;
- Access to be based on clinical need and not upon an ability to pay;
- Aspiring to the highest standards of excellence and professionalism;
- Reflecting the needs and preferences of patients and their relatives and carers;
- Working across organisational boundaries and in partnership with other organisations for the benefit of patients, local communities and the wider population;
- Providing best value for taxpayers' money and the most effective, fair, and sustainable use of finite resources;
- Ensuring accountability to the public, communities and patients that it serves.

19.247 The concept of the NHS Constitution was promoted by the Rt Hon Andy Burnham MP in his first period as a DH Minister. He saw it as a repository of the values of the NHS and a means for all who worked in it to share a common purpose:

> *It was an idea that I first recall reading about in an article by Will Hutton, the writer and journalist, saying that some of the reform journey was creating a sense that the NHS was fragmenting, it was losing its sense of its – its core purpose. And as I went round, I mean, it very much kind of – I was thinking about how do you give people on the ground kind of certainty about what they value? And what they value is the NHS values. Those are the things that get them out of bed in the morning, that's what matters to them, that's why they are working for the NHS. And how do you put those beyond reach – you know, make them absolutely sacrosanct? And that was really – so I picked up the idea from there, but then thought that one of the ways in which you give people the confidence to face a changing NHS was by putting the values very clearly into a – into a constitution. And I'm pleased that that was accepted as a recommendation and then it came into force.*[287]

19.248 He saw it as a work in progress and thought it ought to be debated periodically to consider whether changes to its content were required.

19.249 The position of the NHS Constitution has been reinforced in the Health and Social Care Act 2012 by requiring the Secretary of State to have regard to it.[288] A new edition of the Constitution was published in March 2012, adding a further right in relation to waiting times and a new right, pledge and responsibility for staff in relation to whistleblowing.[289] The Secretary of State is required to review the Constitution every three years and issue a report.

287 Burnham T115.64–65
288 Health and Social Care Act 2012, section 3, adding section 1B to the Health Service Act 2009
289 *The NHS Constitution* (8 March 2012), Department of Health; www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_132958.pdf

19.250 The Constitution received little mention in the evidence before the Inquiry, but clearly has not penetrated to all parts of the healthcare system. For example, Jackie Owen, host on behalf of Staffordshire County Council of Staffordshire Local Involvement Networks, said she had never referred to it.[290]

19.251 David Flory, in a thoughtful passage of evidence, saw the Constitution as a key driver for the development of a positive NHS culture:

> *I think that an effective interaction, relationship, engagement requires systems and processes that enable it to happen and behaviours that can then make it happen. And what the ... significance of the NHS constitution was that we were looking out on a system which, recognising all the issues of independence of foundation trusts that are there now, that we've discussed, the particular roles and responsibilities of regulators, the national headquarters in the Department of Health. What the constitution did, I think, is focus that all of those different contributions, different powers and responsibilities are, therefore, to deliver for patients and for the public, in England, having access to and receiving NHS care. And the importance of putting this in the constitution was to say the way in which we will do that, the way in which all the organisations at national level, for one example, will do that is – it was obviously reflected in change to the health bill on the duty of cooperation. So it was a signal ... to everybody who was looking at this that nationally, we were committed to working in that way. It was part of the commitment to people of England through the NHS constitution, and it set a very clear expectation that, yes, the system and process was there, an expectation of people that their behaviours would be required to work in this way.*[291]

19.252 He suggested that the introduction of the NHS Constitution had had a real impact and cited as an example the 18-week referral to treatment waiting time target, which was a pledge in the Constitution. For the patient there was a form of a remedy, albeit not of compensation:

> *... it means that for patients who are not in receipt of care in line with the pledge in the constitution – have the right to go back to the NHS organisation, the primary care trust, and say, "I want my treatment somewhere else so that I get it more quickly".*[292]

290 Owen T27.98
291 Flory T121.135–136
292 Flory T121.140

19.253 Sir Hugh Taylor pointed to its application in current-day crises in informing action in the public interest that may not be entirely consistent with the theory of the structure, such as when the DH has intervened in ailing FTs, even though it had no power to issue directions to them:

> *I don't think that's an inherent tension. I think, obviously, it's going to be a feature of any managed or regulated system that when things go wrong and urgent action needs to be taken people need to come together to make that happen. I think we learned some lessons from this episode about the need to get on the case to do that earlier, and for all the key players in the system to work more closely together to support an organisation which is going through difficulties. And I think in the end that is what being part of the NHS means. It goes right to the heart of the NHS constitution and, if you like, there comes a point at which you slightly override some of the formal boundaries which exist and work closely together to try and get an organisation or a particular service back on its feet.*[293]

19.254 Professor Ian Cumming, Chief Executive of the WMSHA at the time of the Inquiry's hearings, thought that it was an omission that the Constitution did not make specific reference to the protection that should be afforded to whistleblowers.[294]

19.255 Una O'Brien saw the need to emphasise repeatedly the fact recorded in the NHS Constitution that the NHS belongs to the people:[295]

> *... I think the big cultural shift we need is that that is truly felt at every level of the NHS and we are making progress in that direction in different ways.*

The Department of Health complaints handling

19.256 One area where it might be thought a culture of giving full recognition to the core values of the NHS might have made a difference was in the handling of complaints about poor care received by the DH. As noted above, until Una O'Brien introduced one, there appears to have been no system for a systematic process other than ensuring that MPs' letters were answered by a Minister. Asked why those reading such letters had not reacted by concluding that, whatever the system was, something had to be done, she explained they would not have had any relevant training:

> *THE CHAIRMAN: ... I just wonder whether you have any recollection on why individuals, without naming any of course, in your department who would have received and read such letters wouldn't have had an immediate reaction along the lines of, "Well, I don't know what the system is, but something must be done"?*

293 Taylor T126.32–33
294 Cumming T67.201
295 O'Brien T125.152–53

A. That's a question I ask myself, ... the only way I can possibly understand it is that these are not letters that we deal with routinely and, therefore, it's hard as a person there in a correspondence unit to discern one of those something must be done letters, if routinely you're dealing with correspondence that's on a ... completely different space ... what we've learnt now is that we've actually got to specifically train our staff to show them the sorts of letters that would lead them to ask questions or to say, "There's something not right here. It's not our job to act on it but we do need to make sure somebody is acting on it". And I think we learnt that we've just got to ... the civil servants in the Department ... are they sensitive to the issues they deal with? Yes, indeed they are. But I think that this was genuinely a case of it just not being the normal course of events in the work that people did and, therefore, they weren't sensitised to it and they should have been, and we now have a way of dealing with that.[296]

...

THE CHAIRMAN: You mentioned sensitivity ... would it be possible for such letters to be ignored if the individuals paused to think about the impact on a relative or someone if it were they who were writing that letter and had suffered the experience being described, and is there a sort of personalisation of it that gets missed because of the volumes of correspondences and the remoteness of Richmond House geographically from most of the places the letters are talking about?

A. Yes. Well, I mean, there must be an element of that and to the extent that happens, you know, it is very regrettable and I'm sure it's not intentional.

Conclusions

19.257 The story of Mid Staffordshire is metaphorically one of the bedpan not rattling in the corridors of Whitehall, contrary to the expectations of Aneurin Bevan.

19.258 Senior officials in the DH have accepted that it bears some responsibility for the stewardship of a healthcare system that failed to detect and prevent the deficiencies at the Trust sooner than it did. There is no doubt about the authenticity of their expressions of shock at the appalling story that has emerged from the HCC investigation and the first inquiry report. There is a sense of incomprehension at how this could have come about, and a sense that they believe that others – whether it be the Trust leadership in relation to internal governance, commissioners in monitoring and performance, or the regulators in relation to FT authorisation and compliance with standards – should have done better and that it was unpredictable that they would all have failed to do so.

296 O'Brien T125.121–123

19.259 The Inquiry has heard from some extremely impressive senior officials and former Ministers, all of whom are keen that the lessons of this tragedy should be fully learnt, and they clearly shared these feelings.

19.260 Sir Hugh Taylor told the Inquiry that "failure on the scale revealed at the Trust must also represent a failure of the regulatory and supervisory system as a whole".[297]

19.261 Sir David Nicholson agreed that "the system around that hospital should never have been allowed to fail its patients so badly ... the board of Mid Staffordshire failed in its statutory duties to provide good quality care to its patients."[298]

19.262 Una O'Brien said that "the shock occasioned by what happened at Mid Staffordshire is not merely that individuals failed ... but actually that the system was probably not designed with that scale of unacceptable behaviour in mind."[299]

19.263 Sir Liam Donaldson states that "I didn't think that such a whole scale meltdown was possible."[300]

19.264 It is somewhat telling testimony of the effectiveness of the DH as an institution that it finds itself in this position. It has overseen a system of performance management and regulation that has, throughout the structure, relied in part on the assumption that other parts were working well, leading to a reduction in vigilance in relation to their own responsibilities.

19.265 The sense of shock and disbelief has not led to the DH being inactive since the crisis at Mid Staffordshire, far from it. However, it is not possible to avoid the impression that the action taken, positive in itself, is reactive and, in spite of the much clearer focus on safety and quality that has followed Lord Darzi's report, lacks a sufficient unifying theme and direction to move forward from this point to ensure that the like of this disaster does not happen again.

Structural reorganisation

19.266 In this and other chapters, there has been a review of some of the policy changes over the period under review and before. Each of them was put forward with the intention of improving the standards of the health service. It would be a fruitless exercise to analyse whether or not each was a wise option at the time. Governments are accountable to the electorate for such decisions. It is a fact of political life that Governments of all persuasions will wish to be seen to make improvements to the health service, and take the credit for that. In order to make the measures they want to take, there is an almost invariable resort to

297 Taylor WS00000161953
298 Nicholson WS0000067728
299 O'Brien WS0000059348
300 Donaldson WS0000070174

legislation and structural change. The experiences reviewed in this report tend to suggest that many such changes are not given time to succeed before the next wave of reorganisation occurs. It is open to question whether all have been necessary to achieve the legitimate policy aims lying behind them.

19.267 For example, since 2000 the structure of healthcare systems regulation has undergone three major structural changes (from CHI, to the HCC and Monitor, to the CQC and Monitor). The system for commissioning services has seen a change from health authorities, to PCTs, to a large number of primary care trusts, then a reduction in number and then on to clinical commissioning groups. Public engagement methods have changed from community health councils to a combination of overview and scrutiny committees, and patient and public involvement forums, to local involvement networks and now national and Local Healthwatch. Underlying these changes has in fact been a common direction of travel – a move from a central command and control structure towards a more market- or choice-based system led more autonomously by clinicians close to or at the front line. As this change has occurred, the system of regulation has had to change as well. Changing the structure so frequently to symbolise new steps in this journey has had numerous undesirable consequences. Sir Ian Kennedy offered his experience: "The constant restructuring of the NHS puts at great risk the ideas of continuity, understanding and consistency of organisations."[301]

19.268 Cynthia Bower pointed to the need to prepare for change before implementing it and for time to do this:

> *I believe that the Department of Health should consider what the risks to such organisations are. Efforts are now being made to do this for the forthcoming changes, partly in recognition of the fact that organisational memory can be lost, but it needs to begin long before the new organisation is created, as people who work at the organisation which will be closed down will be looking for new jobs and leaving the organisation. This process did not take place in 2006.*[302]

19.269 The Rt Hon Andy Burnham MP accepted that there was often a disconnect between the policy decisions being made and their practical implementation:

> *I do think that we got the building blocks right with the PCT's and SHA's, however, the difficulty was how this reorganisation happened in practice and we needed to balance that period of turbulence. The reorganisation was a top-down decision driven by Ministers. My view is that unfortunately, sufficient consideration is often not given to how Ministerial*

301 Kennedy WS0000025879, para 159
302 Bower (1) WS0000021021, para 156

decisions will be implemented in practice. Ministers move on, but the impact of their decisions is still being felt for some time later – the political agenda moves on whilst changes are still being managed.[303]

19.270 Among the consequences of reorganisation are the following:

- Significant one-off but repeated financial costs are incurred in redundancies and redeployment of personnel;
- Skills developed in one organisation are often lost in the transfer of functions to others, together with a loss of corporate memory more generally;
- Successful measures are often lost along with those that are not;
- Desirable functions are prevented from being performed by the need to focus on implementing structural changes during transitional stages;
- Lack of stability reduces the authority and standing of organisations that may have or are known to have a limited future;
- Frequent changes of identity, functions and personnel distance organisations from stakeholders;
- Major changes are often made without clarity about how they are to be implemented;
- Pressure of time often means that the new structure cannot be effectively made operational at or before assumption of its responsibilities.

19.271 The effect of this type of change was the subject of comment by many witnesses, but notable was the experience of Anna Walker, a highly experienced civil servant and regulator, of being told within a year of taking up the Chief Executive role of the HCC that it was to be abolished:

The announcement ... was a real body blow to me personally. I cannot remember a time in my professional life when I have felt so challenged personally. I had only recently left the Civil Service to join the [HCC]*. It was a real challenge to be Chief Executive of an organisation which still had important statutory duties to fulfil on behalf of patients while it faced all the consequences of its demise and absorption into another organisation.*[304]

19.272 It has to be open to question whether the same or better results could not often be achieved by a less radical structural and a more evolutionary change, building on what is already in place, exploiting the talents and resources that exist rather than throwing everything away and starting again. Where there are perceived deficiencies, it is tempting to change the system rather than to analyse what needs to change, whether it be leadership, personnel, a definition of standards or, most importantly, culture. System or structural change is not only destabilising but it can also be counterproductive in giving the appearance of addressing

303 Burnham WS0000063415, para 55
304 Walker WS0000028542–543, para 21

concerns rapidly whilst in fact doing nothing about the really difficult issues that will require long-term consistent management.

19.273 The Trust was criticised in the first inquiry report for not undertaking sufficient impact or risk assessment before making significant changes. The same also appears to be the case at a system-wide level. To make this observation is not intended to identify any particular Government, Minister or the DH during any particular period for what has happened in the past, because unfortunately at that level change appears commonly to have been made in this way. However, it is time that there was an immediate change in approach.

19.274 Whilst the NQB has been addressing the transitional risk management required in relation to the current reforms (see above), impact and risk assessments should be made public, and debated publicly, before a proposal for any major structural change to the healthcare system is accepted. Such assessments should cover at least the following issues:

- What is the precise issue or concern in respect of which change is necessary?
- Can the policy objective identified be achieved by modifications within the existing structure?
- How are the successful aspects of the existing system to be incorporated and continued in the new?
- How are the existing skills that are relevant to the new system to be transferred to it?
- How is the existing corporate and individual knowledge base to be preserved, transferred and exploited?
- How is flexibility to meet new circumstances and to respond to experience built into the new system to avoid the need for further structural change?
- How are necessary functions to be performed effectively during any transitional period?
- What are the respective risks and benefits to service users and the public and in particular are there any risks to safety or welfare?
- Is the new system deliverable with the resource and budget allocated to it?

19.275 The level at which such assessments should take place will depend on the level at which the relevant decisions are taken, but in the case of changes requiring legislative reform it is suggested that no Bill proposing healthcare system change should proceed without such an exercise having taken place and been offered to Parliament for scrutiny.

The Department of Health's approach to standards and compliance

19.276 It is to the credit of successive Governments and the DH that they have over the last decade or so recognised the importance of setting standards for the delivery of healthcare rather than merely trusting organisations and professionals to deliver an acceptable service, and assuming that regulation of individual professionals was a sufficient guarantee. However, the

development of a structure that is effective has been very difficult and it is clear that the journey is not yet complete.

19.277 The story of the development of standards within the healthcare system has been one of struggle between the rhetoric of improvement and the need for clarity about what is unacceptable. The experience of Mid Staffordshire has shown that combining aspirations for improvement and minimum process-based standards in a regulatory structure that relied largely on self-assessment cannot be relied on to expose the most egregious failures. The system now administered by the CQC has yet to prove it will be more effective. Many of the concerns exposed in CQC reports appear to have occurred as a result of inspections ordered by the Secretary of State rather than by routine assessment of compliance with standards.

19.278 The reality is that it is not the setting of national standards in itself that will "catch" a Mid Staffordshire, but having effective methods of making realistic measurements, capturing and analysing data, and policing those standards. It is important that such policing is not confined to one method applied by a single organisation, but is undertaken in as many different ways as possible, through provider internal leadership, external but local public scrutiny, commissioning, and the regulator all working to a common set of values, standards and priorities. The DH has struggled to get the balance right between "light touch" regulation and the need to protect service users from harm. Too much may have been expected of regulators in the past, and too much may be expected of the CQC now.

The Department of Health's role in the foundation trust process

19.279 The role of the DH in the development of FT policy, and implementation of it via the FT "pipeline" has been described in *Chapter 4: The foundation trust authorisation process*. The system failed to prevent authorisation of a trust that was completely unfit to be granted the autonomy of FT status. It is an unhappy and concerning story with a number of disturbing features:

- Financial and corporate governance criteria were allowed to predominate over clinical quality considerations;
- Standards were lowered to allow more trusts through to Monitor's assessment process;
- The system for obtaining the Secretary of State's approval was not fit for purpose;
- The DH's internal system failed to bring to the responsible Minister's attention all the matters needed for an informed decision on the Trust's case;
- There was a lack of clarity between the DH and Monitor as to what the approval of the Secretary of State meant;
- The DH was aware of the difficulties in relationships between the HCC and Monitor. It is impossible to say what part, if any, these played in the failure of effective communication of the HCC's concerns to Monitor, but they cannot have assisted. The DH had a responsibility in the interest of protecting patients' interests to seek to resolve such

difficulties. It should not in this instance be able to distance itself from it by suggesting it was entitled to rely on the assessments of those two organisations.

The Department of Health's priorities and culture

Clinical resources and involvement

19.280 The DH has had the advantage of highly impressive senior clinical figures all of whom are clearly dedicated to making the NHS work for the people it serves and dedicated to inculcating a culture of focus on patient care and safety. Conspicuous among these have been its Chief Medical Officer during the relevant time, Professor Sir Liam Donaldson; the NHS Medical Director, Professor Sir Bruce Keogh; and Dame Christine Beasley, the former Chief Nursing Officer for England. Sir Liam campaigned with distinction and with determination for the needs of patient safety to be recognised. Sir Bruce gave illuminating and insightful evidence to the Inquiry, for instance on his reaction to the May 2008 letter from HCC.[305] Dame Christine clearly recognised the need to reform nursing for the benefit of patients.

19.281 Despite the existence of such a resource, senior clinicians may not have been at the heart of decision-making on some key issues that have been examined at this Inquiry. For example:

- Clinical input seems to have been missing from the FT application process at the time of the Trust's application;
- The HCC letter alerting all to the serious concerns arising out of the investigation of the Trust was not seen by Sir Bruce or Sir Liam.

19.282 The DH should ensure that there is senior clinical involvement in all decisions that may impact on patient safety and well-being.

19.283 The DH has, of course, a range of senior clinicians at its disposal, including, from 2009, 20 National Clinical Directors, but will no doubt be mindful of the need to ensure that there is senior clinical involvement in all decisions that may impact on patient safety and well-being. Since the events in question, there has been a significant and welcome increase in the clinical involvement in the FT process. For example the NHS Medical Director is now given oversight of the DH's consideration of support for an FT application.[306]

305 DF/15 WS0000066952; T123.42–45
306 Holden T120.82

Focus on patients

19.284 This chapter contains several episodes in which it is unlikely that reactions to information would have been the same had there been a focus on patient safety or well-being:

- Those receiving complaints did not react to the implications of what was contained in them by exhibiting a determination that the problems exposed should be addressed. The current Permanent Secretary sought to assure the Inquiry that this could be remedied by training and a system, but neither will succeed unless all DH staff are persuaded to think first in everything they do of the implications for patient safety and welfare;
- There was no immediate reaction to knowledge of the difficulties between the HCC and Monitor even though this had the potential of creating a regulatory gap;
- The reaction to information about the HCC investigation of the Trust as it progressed was to rely on the HCC or Monitor to recommend special measures if they deemed it necessary. There is no doubt on the basis of the evidence considered above that senior officials and the Minister did discuss the issue of the investigation on numerous occasions with the HCC and were assured that the Trust was cooperating. There was no indication that the HCC sought any intervention. The DH cannot be criticised for not seeking to be informed. Quite properly the DH and its officials would have been concerned not to interfere with the independence of action of the regulator. However, through the SHA and the PCT it had responsibilities with regard to the performance management of the commissioning process. The evidence from senior officials such as Sir David Nicholson and Sir Bruce Keogh suggests that if the opportunity had been taken at times to make a departmental judgement of the adequacy of the actions in train, more might have been done in conjunction with the commissioners at an earlier stage to ensure the protection of patients. No separate judgement about such matters was made in the DH, relying as it did on the assurances of the regulator. It was not unreasonable to expect the regulators to do their jobs properly and to respect their independence, but it is difficult to believe that any reader of the concerns raised by the HCC who thought about the potentially continuing impact on patients of the deficiencies identified would have taken such a passive stance. Mr Bradshaw, for one, having read the HCC report, felt the assurances that had been given were wrong. Hesitancy in making such a judgement can only have been informed by an institutional instinct that focused on respect for systems rather than the real impact on individual service users.
- Likewise, it is difficult to understand the impact many witnesses said the HCC report had as compared with either the interim letters from the HCC or the draft findings of fact. The evidence gives no sense that the DH anticipated the crisis unfolding until very shortly before the final report arrived. Any careful reading of the draft findings of fact should have caused serious and urgent concern about the state of the Trust and the risks potentially being run by patients there. The fact that the Secretary of State was left unaware of this until it was raised with him by Sir Ian Kennedy is eloquent testimony of this. The argument advanced to justify its inaction, that the DH had to respect the independence of the

regulators, rightly, did not prevent a form of intervention later in ensuring appropriate appointments were made to the Trust.

19.285 Undoubtedly, all the DH witnesses seen at the Inquiry are genuinely committed to public service and believe that they work for the good of patients. However, the evidence shows that DH officials are at times too remote from the reality of the impact of the service they oversee on patients. They need to connect to it more by visits, perhaps even work experience, but most importantly by personal contact with those who have suffered poor experiences. Listening to the experiences described in person at the first inquiry and the present one have been strong evidence of the value of doing so. Nothing is more likely to focus the mind on the impact of decisions on patients than to listen to patients' experiences. The DH could also be assisted in its work by involving patient/service user representatives through some form of consultative forum within the DH. In the end, the most important cultural change should be to require all who work there to place the patient perspective at the forefront of their minds and deliberations in all they do.

The Department of Health as a cultural leader

19.286 Consideration has been given above to management consultants' reports containing suggestions of a bullying culture in both the NHS and the DH. The evidence before the Inquiry does not justify a conclusion that there is in fact a culture within the DH that could properly be described as one of bullying. What the evidence does establish is that, at times, quite proper decisions and directives emanating from the DH have either been interpreted further down the hierarchy as bullying, or resulted in being applied inappropriately at local level, and not as intended, in an oppressive manner. It is not the intent that is in question, but the unintended consequences and perceptions of others as a reaction to the DH's requirements. The management consultants' reports contain evidence of these perceptions. The bullying apparent in the Trust's A&E is an example of the unintended consequence of the pressure applied down the hierarchy to comply with access targets. Whilst the rejection by senior witnesses of the suggestion that there was a bullying culture in the DH was understandable, as was their sense of outrage, there is a need to reflect, with insight and self-criticism, on how such perceptions and effects could be avoided in future. Merely protesting that it is not true is not enough.

19.287 There needs to be a careful balance between stating with clarity policy requirements, in particular by avoiding tolerance of unacceptable standards of performance, and unintentionally incentivising short cuts to compliance by applying implicity career-threatening pressure to uphold such standards. The pressures applied to Trust executive officers is very great, and perhaps rightly so, but it is not a sign of a healthy system that the turnover in senior posts is so great.

19.288 It is important to make clear that it is not suggested that properly designed targets, appropriately monitored, cannot provide considerable benefit to patients and serve a useful purpose. Indeed, the Inquiry accepts that they can be an important part of the health system in which the democratically elected Government of the day sets its expectations of providers who are funded by the taxpayer. Nevertheless, steps have to be taken to guard against the possibility that some providers will strive to meet targets at the expense of delivering safe and effective care to patients and this can take the form of inappropriate bullying, as occurred at this Trust.

19.289 The issue is easier to identify than the solution, but various recommendations are made in *Chapter 24: Leadership in healthcare*. So far as the DH itself – and its operational arms such as the NHS Commissioning Board – is concerned, it must ensure that performance requirements are always expressly balanced by provision of qualifications to allow: patient safety and well-being to remain the priority; resources and support that enable the requirements to be met; and restriction of suggestions of adverse career consequences to cases of misconduct or serious incompetence.

19.290 It is a truism that organisational culture is informed by the nature of its leadership. The DH has an important leadership role to play in promoting the change of culture required throughout the healthcare system. This is considered in *Chapter 20: Culture*, but some examples of where such cultural leadership could be applied may be mentioned here:

- Whilst positive encouragement of good performance is necessary, communication of requirements to remedy deficiencies should not be disguised or diluted by positive reports. There is a tendency throughout the health system to water down justifiable and constructive criticism by inserting it among passages praising other aspects of performance. It is justifiable for regulators and performance managers to identify and disseminate examples of good practice, but it is their principal task to seek out and correct non-compliance with standards.
- The DH and its Ministers understandably wish to publicise the many achievements of the NHS: it is only right and proper that they do so. What must be avoided, however, is an approach that seeks to minimise the gravity of failings that have been uncovered by reference to those achievements. Deficiencies in the provision of care to a group of patients are emphatically not mitigated by the provision of good service to another group.
- The DH must lead and promote transparency in the health service. This requires all organisations:
 - To be open about deficiencies that have occurred, in particular where they have harmed patients;
 - To ensure that anyone harmed by poor care is made aware of this and offered a suitable remedy;
 - To make information publicly available about performance at the most detailed level possible as well as accessible summaries.

Providing the base for a uniform health service culture

19.291 The very complexity and size of the NHS presents challenges in creating and maintaining a positive patient-focused culture throughout. This challenge will increase as the autonomy of front-line organisations increases and each becomes more susceptible to the vagaries of local leadership. The DH has primary responsibility for providing the means for developing a consistent culture. Two measures will help it to do so:

- Development and promotion of the NHS Constitution. This should be refined to be the repository of the core values to which all individuals and organisations in the system must hold to in their work, and in general terms the rights of patients and the obligations of the system and those who work in it. It should not be a document that requires the lengthy and complex guidance that currently accompanies it, but should be capable of being fully understood and accepted by all. It should be handed to all new employees with their contract, which should oblige them to uphold it.
- Alignment of standards and guidance into a coherent structure. At the moment the Essential Standards are independent of NICE quality standards, with guidance from multiple sources. All of these should be informed by high-level patient outcome measures that will be separated into fundamental safety and quality standards, and other more discretionary enhanced and developmental standards of excellence and improvement. Quality standards and guidance should so far as possible be included in one universal and easily accessible source in which they should be accorded a significance proportionate to the evidence base (clinical and consultative) supporting them, together with the means of measuring compliance.

19.292 These points are considered in the chapters which follow.

Summary of recommendations

Recommendation 286

Impact and risk assessments should be made public, and debated publicly, before a proposal for any major structural change to the healthcare system is accepted. Such assessments should cover at least the following issues:

- What is the precise issue or concern in respect of which change is necessary?
- Can the policy objective identified be achieved by modifications within the existing structure?
- How are the successful aspects of the existing system to be incorporated and continued in the new system?
- How are the existing skills which are relevant to the new system to be transferred to it?
- How is the existing corporate and individual knowledge base to be preserved, transferred and exploited?
- How is flexibility to meet new circumstances and to respond to experience built into the new system to avoid the need for further structural change?
- How are necessary functions to be performed effectively during any transitional period?
- What are the respective risks and benefits to service users and the public and, in particular, are there any risks to safety or welfare?

Recommendation 287

The Department of Health should together with healthcare systems regulators take the lead in developing through obtaining consensus between the public and healthcare professionals, a coherent, and easily accessible structure for the development and implementation of values, fundamental, enhanced and developmental standards, as recommended in this report.

Recommendation 288

The Department of Health should ensure that there is senior clinical involvement in all policy decisions which may impact on patient safety and well-being.

Recommendation 289

Department of Health officials need to connect more to the NHS by visits, and most importantly by personal contact with those who have suffered poor experiences. The Department of Health could also be assisted in its work by involving patient/service user representatives through some form of consultative forum within the Department.

Recommendation 290

The Department of Health should promote a shared positive culture by setting an example in its statements by being open about deficiencies, ensuring those harmed have a remedy, and making information publicly available about performance at the most detailed level possible.



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